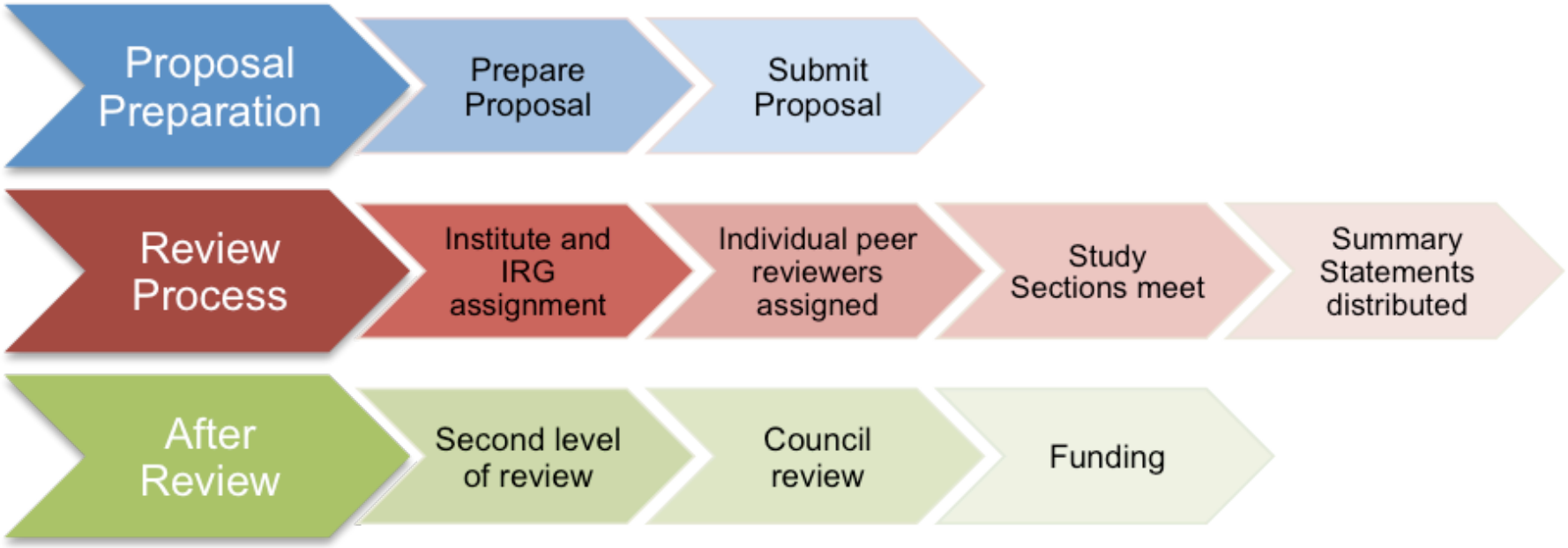
Peer review at NIH

Erica Whitney
Senior Research Development Analyst

Berkeley Research Development Office

Updated May 2013 Kim Baeten

NIH Review Process



Goals of the Changes (per NIH)

- 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.

NIH Review Criteria

- Significance: Does this study address an important problem? If the aims of the application are achieved, how will this advance scientific knowledge? What will be the effect of this study on the concepts or methods that drive this field?

NIH Review Criteria

- Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? For applications designating multiple Project Directors/Principal Investigators (PDs/PIs), is the leadership approach, including the designated roles and responsibilities, governance and organizational structure consistent with and justified by the aims of the project and the expertise of each of the PDs/PIs?

NIH Review Criteria

- Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

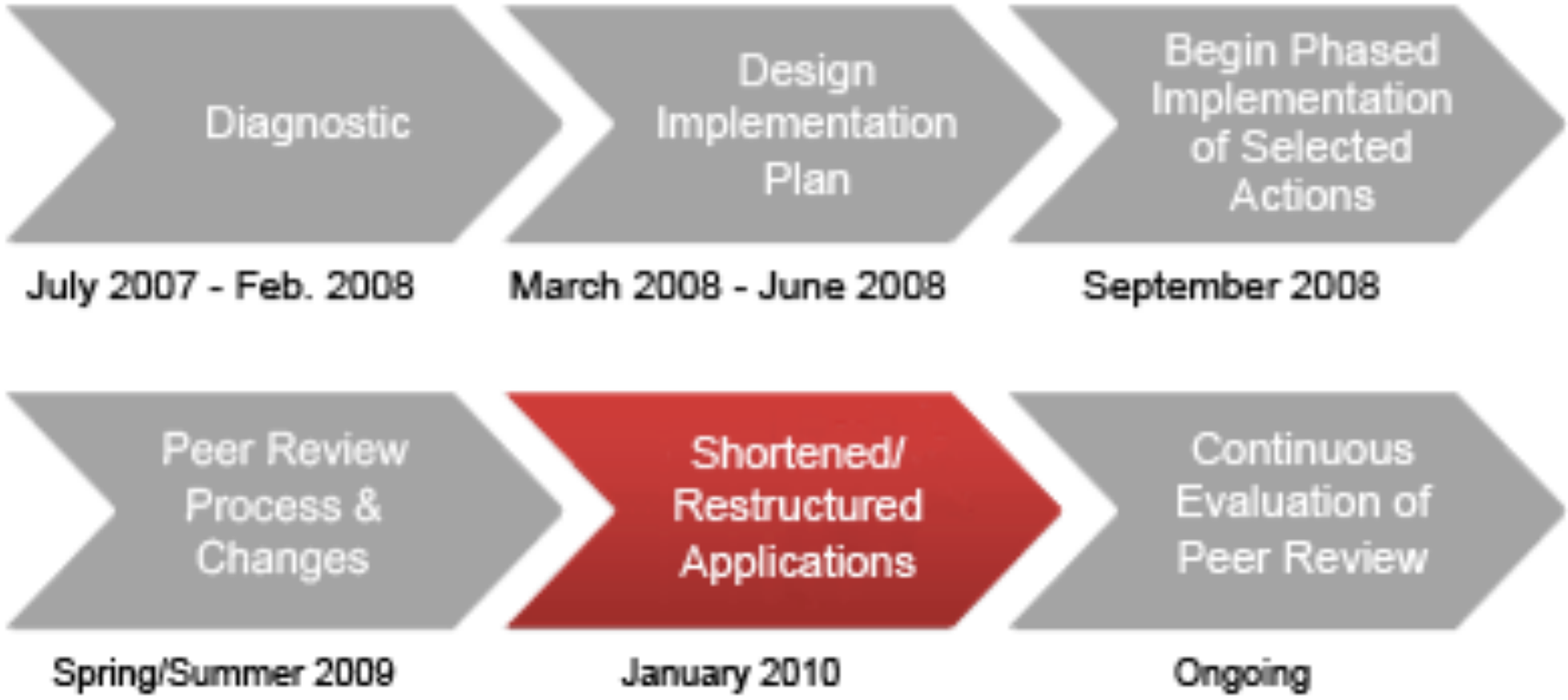
NIH Review Criteria

- Investigators: Are the PD/PI(s) and other key personnel appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI(s) and other researchers? Do the PD/PI(s) and investigative team bring complementary and integrated expertise to the project (if applicable)?

NIH Review Criteria

- Environment: Do(es) the scientific environment(s) in which the work will be conducted contribute to the probability of success? Does the proposed study benefit from unique features of the scientific environment or subject populations, of employ useful collaborative arrangements? Is there evidence of institutional support?

Enhancing Peer Review



Fund the best science, by the best scientists, with the least amount of administrative burden.

BRDO

Implementation Plan

- **Priority 1 – Engage the Best Reviewers -** The excellence of peer review is directly correlated with the ability to recruit and retain the most accomplished, broad-thinking, and creative scientists to serve on NIH study sections.

- **Priority 2 – Quality & Transparency of Review -** The peer review process must strive for maximum clarity, fairness, and consistency and help applicants determine a best course of action once reviewed. The process of review should focus on the potential impact, originality, and feasibility of the proposed research.

Implementation Plan

- **Priority 3 – Provide Balanced and Fair Reviews Across Scientific Fields and Career Stages -** Peer review should fairly evaluate proposals from all scientists, regardless of their career stage or discipline, and avoid bias towards more conservative and proven approaches at the expense of innovation and originality.

- **Priority 4 – Continuous Review of Peer Review -** The last priority is to develop a permanent process for continuous review of peer review. Peer review should continuously adapt itself to the evolution of science. The NIH peer review process will commit to a continuous quality control and improvement process based on a rigorous and independent prospective evaluation that favors innovative approaches to review and program management.

Phased Implementation (10/08-02/09):
New Policies on New and Early Stage Investigators

NOT-OD-09-013. For FY 2009, NIH expects to support New Investigators at success rates equivalent to that of established investigators submitting new applications. The majority of New Investigators supported in FY 2009 are expected to be Early Stage Investigators (ESIs).

NOT-OD-08-121. New Investigators within ten years of completing their terminal research degree or within ten years of completing their medical residency will be designated Early Stage Investigators (ESIs).

Phased Implementation (10/08-02/09):
New Policies on New and Early Stage Investigators

NOT-OD-09-021. All New Investigators must update their eRA Commons profiles to ensure that they are given appropriate consideration for R01 applications for February, 2009 due dates and beyond. The degree date information requested in the profile and eventually the date of completion of medical residency will be used to determine ESI eligibility.

NOT-OD-09-034. Some new investigators will experience a lapse in their research or research training or they will experience periods of less than full-time effort during the 10 year ESI period. In order to accommodate such lapses, the NIH will consider requests to extend the ESI period.

http://grants.nih.gov/grants/new_investigators/index.htm

Shortened/Restructured Applications

- Changes to Application Structure
  - Research Strategy section replaces Background and Significance, Preliminary Data, and Research Design and Methods sections.
  - Biosketch and Resources changes.
- Changes to Application Length
  - 12 pages for R01 research strategy
  - 6 pages for R03/R21 research strategy

Continuous Evaluation of Peer Review

- Online surveys (applicants, reviewers, Councils).
- Data-driven mechanisms to evaluate review outcomes.
- Peer review pilots and assessment of those pilots.

Review: Guidance for 9-point ratings

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	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
Low	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

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

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

Overall Impact

- Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

Overall Impact

- Is not a 6th review criterion.
- Is not necessarily the arithmetic mean of the scores for the scored review criteria.
- Takes into consideration, but is distinct from, the scored review criteria.
- Is the synthesis/integration of the five core review criteria that are scored individual and the additional review criteria which are not scored individually.

Overall Impact

To evaluate, the reviewer(s) make an assessment of the *likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the scored review criteria, and additional review criteria (as applicable for the project proposed).*

- Likelihood (i.e., probability) is primarily derived from the investigator(s), approach and environment criteria.
- Sustained powerful influence is primarily derived from the significance and innovation criteria.
- Research field(s) may vary widely, so it would be helpful if reviewers identify in their reviews the research field(s) they believe will be influenced by each project.

Overall Impact?

impact = function (importance [significance, innovation],
(likelihood [approach, investigator, environment])

Overall Impact

For fellowship applications:

- Should reflect likelihood that the fellowship will enhance the candidate's potential for, and commitment to, a productive independent scientific career in a health-related field.

Overall Impact

- See case studies in your handout.

Guidelines for Reviewers

- Detailed guidelines for reviewers available here:
  - http://grants.nih.gov/grants/peer/reviewer_guidelines.htm
  - http://cms.csr.nih.gov/PeerReviewMeetings/ReviewerGuidelines/

Critique Template

RPG/R01/R03/R15/R21 Review

If you cannot access the hyperlinks below,

visit http://grants.nih.gov/grants/peer/critiques/rpg.htm.

Application #:

Principal Investigator(s):

OVERALL IMPACT

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five scored review criteria, and additional review criteria. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Overall Impact
Strengths • **Weaknesses** •

Critique Template

1. Significance
Strengths • **Weaknesses** •

2. Investigator(s)
Strengths • **Weaknesses** •

3. Innovation
Strengths •

Critique Template

- Responses for Protections for Human Subjects, Vertebrate Animals, and Biohazards **are required for all applications**.
- A response for Inclusion of Women, Minorities and Children **is required** for applications proposing Human Subjects Research.

Protections for Human Subjects
Click Here to Select Comments (Required Unless Not Applicable): • Data and Safety Monitoring Plan (Applicable for Clinical Trials Only): Click Here to Select Comments (Required Unless Not Applicable): ○

Inclusion of Women, Minorities and Children Applicable Only for Human Subjects Research
Click Here to Select Gender Code

Critique Template

ADDITIONAL REVIEW CONSIDERATIONS

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations
Click Here to Select Comments (Required Unless Not Applicable): •

Select Agents
Click Here to Select Comments (Required if Unacceptable): •

Resource Sharing Plans

Critique Template

ADDITIONAL COMMENTS TO APPLICANT

Reviewers may provide guidance to the applicant or recommend against resubmission without fundamental revision.

Additional Comments to Applicant (Optional)
•

Critique Template

- See example R01 review in handout.

What Happens Before Study Section

- Reviewers go into eRA Commons and choose Internet-Assisted Review (IAR) to download material for review.

IAR allows for:

- Critique and preliminary score submission and modification.
- Acceptance of critiques in Word (*.doc) or plain text (*.txt) format.
- Streamline voting.
- Electronic posting of additional meeting materials for Reviewers to read.

What Happens at Study Section

- Sitting in assigned seats in some kind of circular fashion.
- Program officer not usually in the room, but may be listening on the phone.
- SRO and Chair of the meeting are "in charge."
- SRO goes over the rules (e.g., we're not here to decide funding, we're here to look at the science not whether the science is fundable or anything like that; if you have conflicts get out...; don't discuss proposals outside of this room with anyone...; etc.).
- Chair takes over. Describes triage process. He conducts the meeting and has a schedule to keep to.

What Happens at Study Section

- Chair introduces the first proposal. Proposals are usually presented in order of highest average score to worst. Everything available online. So, you start out by knowing who's best to worse.
- *Primary, secondary and tertiary reviewers*. Chair asks for all scores. Primary gives overview or his/her summary. Then all reviewers summarize their bullet points for each review criteria, starting with primary. Secondary is supposed to add what the primary missed. Chair will ask him to not duplicate primary. Tertiary often doesn't speak.
- Chair can moderate discussion. Sometimes there's debate or disagreement, and chair can keep things moving or from getting bogged down in detail. Keeps people from talking about funding.

Procedure for Discussed Applications

- Assigned reviewers discuss strengths and weaknesses of each application.
  - Recommend overall impact/priority score.
  - Criterion scores are not discussed by the committee.
- All eligible members record an overall impact/ priority score.

What Happens at Study Section

- Final scores given by primary, secondary, and tertiary. Then chair tells study section what the range is going to be and asks if anyone is going to vote outside the range. Usually you have to justify your score if you are voting outside the range.
- Move on to the next proposal, and the cycle continues.
- Better proposals generally have less discussion because there is more agreement. Middle and bad scores get the most discussion. Debate over everything from innovation and significance to methods. Less often debate over investigator.

What Happens After Study Section

- Reviewers are given a chance to modify their critiques and associated criterion scores in IAR.
- Scores are posted to applicant's eRA Commons account within a few days of the meeting.
- Summary Statements are compiled and written by the SRO and released about 2 months later.

Scores

- Overall impact/priority scores of discussed applications will be the mean of scores voted by all eligible reviewers, multiplied by 10.
- Final scores will range from 10-90, in whole numbers.
- Summary statements for ALL applications will include the criterion scores and critiques posted by assigned reviewers.

Percentiling

- Scores are percentiled to the appropriate base (e.g., the study section base if there are ≥25 R01 applications or a CSR-all or IC-all base if <25).
- All percentiles are rounded to a whole number.

Percentiling

- A percentile ranks your application relative to the other applications reviewed by your study section at its last three meetings.
- A percentile roughly translates to the percentage of applications receiving a better overall impact score from the study section during one year.
- Percentiles range from 1 to 99 in whole numbers. Rounding is always up, e.g., 10.1 percentile becomes 11.
- A lower number indicates a better score.

http://nexus.od.nih.gov/all/2011/03/08/overall-impact-and-criterion-scores/