

What happens after you submit your application?

Overview of the grant process

- Receipt and referral
- Grant sent to assigned reviewers; each provides preliminary scores and a written review. The preliminary scores are used to decide which grants will be discussed.
- Discussion at meeting. After discussion, all reviewers submit final scores. Assigned reviewers can change their initial score after the discussion.
- Advisory Council review
- Funding decisions and notification

Receipt & Referral

- Center for Scientific Review is the receipt point for:
- Checks for completeness
- Determine area of research
- Assigns application to specific NIH Institute or Center for possible funding
- Assigns an identification number
- Assigns application to a Scientific Review Group (SRG or "Study Section")

Referral to Study Sections

Referral to study section is based on:

- Grant mechanism
- Referral Guidelines (i.e., scientific topics covered by each study section; published on NIH website)
- Most applications are referred to study sections administered within CSR (e.g., R01)

Review outside CSR (institutespecific programs)

- F31s, F32s, Ks, and NIDCD R03s are reviewed "in house" by the NIDCD Scientific Review Branch (SRB). The NIDCD SRB is part of NIDCD, not CSR.
- CDRC is the NIDCD's standing study section; other NIDCD study sections are ad hoc (members are recruited each round based upon the science that needs to be reviewed).
- F31s/F32s will be reviewed by ad hoc study sections.

Getting assigned to the "right" Study Section

- Request that your application be reviewed by a specific study section in the electronic cover letter when submitting your application to Grants.gov
- You can also request a particular reviewer not be assigned if you consider they have a bias (e.g., disagrees with your research point of view). That request may or may not be honored.

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Assigned reviewer and study section roles

- Assigned reviewers (members of study section) evaluate scientific and professional merit of applications and submit written critiques, preliminary "criterion" scores and preliminary "overall impact" scores (more on scores later)
- Study section convenes to:
 - Confirm which applications are discussed (based on average of initial impact scores from assigned reviewers)
 - Discuss highest ranking scored applications
 - Assign final impact scores

How are the assigned reviewers chosen?

- Primary, secondary & tertiary reviewers are usually individuals with most extensive background in area of proposal. These reviewers are required to carefully read/review the grant and write up their review.
- Each reviewer is assigned to a number of grants (~12) to write formal critiques and assign overall impact scores + subscores, in advance of the meeting.

What do the assigned reviewers do when they read the proposal?

- Read Specific Aims to get overall impression
- ■Read through grant and make notes
- ■Note strengths and weaknesses for each review criterion
- Weigh the strengths and weaknesses to come up with a score on each element
- Each assigned reviewer submits written critique + scores (in Commons)

Study Section

- Consists of 10-20 individuals inside and outside your area of interest/expertise. Some members have multi-year appointment, some are ad-hoc members for that meeting only. Smaller groups may be convened for ad hoc reviewing
- Study section membership
 - AUD

http://www.csr.nih.gov/Roster_proto/sectionI_list_detail.asp?NEWSRG=AUD&SRG=AUD&SRGDISPLAY=AUD

LCOM

http://www.csr.nih.gov/Roster_proto/member_roster.asp?srg=LCOM&SRGDISPLAY = LCOM&CID=102251

MFSR

http://www.csr.nih.gov/Roster_proto/sectionI_list_detail.asp?NEWSRG=MFSR&SRG
=MFSR&SRGDISPLAY=MFSR

Who runs the meeting?

- The review session is conducted by the Scientific Review Officer (SRO) and the Study Section Chair.
- The SRO is an extramural staff scientist responsible for ensuring that each application receives an objective and fair initial peer review, and that all applicable laws, regulations, and policies are followed. The SRO recruits reviewers and assigns the applications.
- The Chair is a member of one of the disciplines reviewed by the study section, moderates the discussion of scientific and technical merit of the applications, and also serves as an assigned reviewer for some of the grants.

Which grants will be discussed?

- Grants are ranked based on their preliminary scores. Grants below the 50% point receive written reviews, but are not scheduled for discussion.
- Prior to the meeting, reviewers have a chance to see others' written critiques and scores. Any reviewer can request that a grant <50% point be included in discussion.

How are conflicts handled?

- If you are a member of study section and submit a grant, your grant will be reviewed elsewhere.
- Reviewers in conflict (i.e., at same institution, or who have collaborated with the grant investigators) are not present during discussion, and do not score the grant

The Scores

The "New" NIH Scoring System involves two inter-related parts

Criterion scores

Overall impact scores

+ Scoring System

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

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Criterion Scores

- Criterion scores are given separately for each category, and are intended to convey how each assigned reviewer weighed the strengths and weaknesses of each section
- Significance
- Innovation
- Investigator
- Approach
- **■** Environment

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5 Categories

- Significance

- · Will this make a difference
- · Move the field ahead
- Importance of the problem

Investigators

- Productivity in high quality journals
- Past research grants
- Known for solid track record of good quality research
- Worked on the problem before
- Publication using techniques
- Are all of the necessary skills covered by the investigative team



5 Categories continued

- Innovation

- Is this a new approach or only a replication
- A timely approach
- A logical step
- Useful to the field
- A new paradigm

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Categories continued

Approach

- · Are the methods sound
- Have they considered alternatives
- Rationale for methods
- Power Analysis
- Statistical methods provided
- · Realistic amount of work given time and staff

- Environment

- Are the instruments available and already being used
- Are they using grant to build a lab
- Research Infrastructure there—Center support, i.e. statistics; access to appropriate subject population
- Good collaborators available
- Shared Facilities

Impact Score

Reviewers 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 (e.g., new investigator). An application does not need to be strong in all categories to be judged likely to have major scientific impact.

■ The impact score for the application is not intended to be an average of criterion scores

Common weaknesses: Significance

- Lacking or weak theoretical framework
- Aims are not hypothesis-driven
- Weak or unclear motivation ("a lack of information" is not necessarily a motivation)
- Poor integration of existing literature (be sure to consider the likely reviewers' contributions!)
- Weak connection to human health

Common Weaknesses: Environment

- ■Institutional commitment is weak
 - PI does not have appropriate release from other responsibilities
- ■Infrastructure is weak
 - Lack of appropriate technology, tech support,
 - committed space
 - Subjects not available
- **■**Community is weak
 - Lack of a scientific community to provide consultation

Common weaknesses: Investigator

- Weak publication record / trajectory relative to career stage
- Non-productive post-doc training, unpublished dissertation research, unproductive prior grant support (perception is that supported work won't be published)
- PI lacks training in methods or analysis, no collaborator to offset this weakness
- No formal plan for collaborators to interact
- Team lacks expertise (supported by pubs) in essential area

Common weaknesses: Innovation

- ■Techniques are not current or appropriate
- ■Too incremental
- Just not interesting
 - "Among the infinite questions that *could be* asked, is this the one that most deserves to be addressed?"
 - Does it advance an important scientific area?

Common Weaknesses: Approach

- Overly ambitious betrays naiveté
- Feasibility of sample size, population, techniques not demonstrated
- Sample size not supported by power analysis, preliminary data, using reasonable effect size

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Example

1. Significance: 2

Strengths:

- This proposal's topic has significant implications for the nation's health
- The PI plans to explore two promising mechanisms implicated in the cause of X and, as such, findings from this project could meaningfully advance our understanding of X

<u>Weaknesses</u>

■ The proposal's Specific Aims section does not provide sufficient rationale for the study of X, its importance for the nation's health, and how the planned study's findings will further our theoretical and/or clinical approach to X

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Example

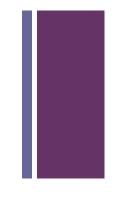
2. Investigator: 1

Strengths

- The investigator has been productive in recent years, especially in areas pertinent to this proposal.
- The investigator has developed a strong research team.
- The investigator has included prominent, world-class consultants
- The investigator has seemingly been responsive to previous reviews

Weaknesses

■ None apparent



Example

3. Innovation: 3

Strengths

■ The project is innovative in that it proposes to study the pathogenesis of X

Weaknesses

■ Although PI makes apparent his/her expertise and ability to successfully use his/her proposed approach, there are lingering concerns whether findings will be go beyond versus essentially confirm findings of previous research.

Example

4. Approach: 2

Strengths

■ • The PI has seemingly improved his/her approach, making it more suitable for addressing his/her hypotheses and research questions.

Weaknesses

■ The format of the "Significance" section makes it quite difficult to appreciate the contribution these studies make to the application. A more consistent format would have greatly improved reviewer understanding of the rationale/approach/findings/implications of the various preliminary studies

Example

5. Environment: 1

Strengths

■ The environment, personnel and consultants are excellent and appropriate to the proposed plan of study

Weaknesses

■ None apparent

■ Further Comments for the PI:

The Discussion

- Preliminary impact scores given (without discussion)
- Primary reviewer speaks first, followed by secondary and tertiary reviewers. Latter reviewers encouraged to raise new information or disagreement, not just to repeat 1st reviewer's comments
- Discussion by group. It's not unusual for there to be someone with relevant experience who was not an assigned reviewer. Any member of the study section can comment on any other proposal.

Final Scores

- Key reviewers state final impact scores (may be different than initial scores). Reviewers are guided use the full range of the rating scale and spread their scores to better discriminate among applications
- Everyone submits their scores to online system. Panel members must state if scoring "outside the range" (of the assigned reviewers). If far outside the range/have additional concerns, may be asked by chair to write brief critique for the PI.
- Administrative issues (Human Subjects, vertebrate animals, budget) are discussed but not scored. However, poor attention to administrative issues may "color" reviewer's impressions.

+ Final Scores

- After the meeting, individual reviewer scores will be averaged and the result multiplied by 10 to determine the final impact score
- The range of the final application scores is from 10 through 90

Grants not discussed

■ If not discussed, the PI receives the three written critiques from assigned reviewers, plus subscores. No final impact score is provided.

Other "nonscored" categories:

- Not Recommended (NR); occurs by majority vote of the SRG members if: application lacks significant merit or presents serious ethical problems in protection of human subjects or use of vertebrate animals, biohazards, and/or select agents. NR applications do not proceed to Council
- DF: Deferred (lack of sufficient information, lack of a quorum, allegations of research misconduct)
- AB: Abstention (rare)
- CF: Conflict (score put in by a reviewer who is in conflict with the application)

Summary Statement

- Face page with overall impact score (and percentile rank for many mechanisms)
- Summary of Discussion (written by the primary reviewer, with input from the other assigned reviewers)
- Abstract
- Three critiques. Each assigned reviewer has opportunity to edit their critique if needed, following the discussion.
- Human Subjects, Vertebrate Animals and administrative items (Budget, Biohazards, Training in the Responsible Conduct of Research)

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(NIH) Peer Review: After the review

- Overall impact score released and appears on eRA
 Commons https://commons.era.nih.gov/commons/
- Assignment of percentile rank
 - All proposals that come to study section for particular round of review are pooled
 - Pool divided up by budgeted subgroups (i.e., R01s do not compete with R03s)
 - Percentile ranks established within subgroups;
 - How many proposals submitted, the quality of these proposals, amount of money available, all influence the payline, more or less...
- Summary Statement released and appears on eRA Commons.
 Once released, information is available to you, NIH program staff and ultimately to Institute's National Advisory Council

Deciding who gets funded

- Review by National Advisory Council to make funding recommendations based on scientific merit, program priorities and availability of funds.
 - This is where scores that are "on the bubble" might be funded.
- Grants within the "automatic" payline are typically funded
- May also be funded based on identified needs of the institute (e.g., institute desires to have a balanced research portfolio)

Special categories for investigators

- New Investigator: An NIH PI who has not yet competed successfully for a substantial, competing NIH research grant (e.g., an R01). May have opportunity to write response letter prior to Council review.
- Early Stage Investigator (ESI): within 10 years of completing his/her terminal research degree or within 10 years of completing medical residency (or the equivalent)

Funding decisions & notification

- Institutes make final funding decisions based on National Advisory Council's recommendations
- If funded, Program Officer (PO) works with applicant and Grants Management Officer (GMO) to set budget and terms of award, and resolve any remaining administrative issues.
- Grants Management Officer (GMO) issues Notice of Grant Award (NGA) to your institution, interacts with applicants' institutional business officials, and manages financial/business aspects of awards

Websites with more information about writing and submitting a grant to NIH

■ Youtube with demonstration of review process
http://public.csr.nih.gov/aboutcsr/contactcsr/pages/contactcorvisitcsrpages/nih-grant-review-process-youtube-videos.aspx

■ Information and links to other helpful websites

http://public.csr.nih.gov/aboutcsr/NewsAndPublications/Publications/Documents/yourapplicationflyer.pdf