NIH Grant Reviews Information Packet

(Compiled by Scott Thomson, 18 Aug 2009, thomson@byu.edu)

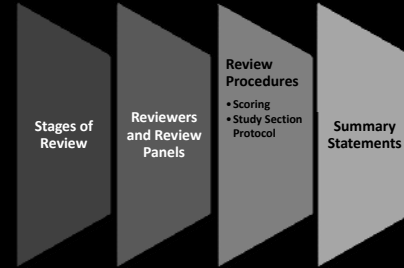| Item	Description
1	Grant Review Handout from Scientific Review Officer (SRO)
2	Notes from Grant Review Training Workshop
3	Scoring System & Procedure
4	Insider's Guide to Peer Review for Applicants
5	Research Project Grants: Summaries & Definitions

The NIH Grant Review Process

Christopher A. Moore, Ph.D., Scientific Review Officer
National Institutes of Health, National Institute on Deafness and Other Communication Disorders
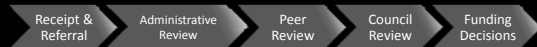

Overview

Stages of Review → Reviewers and Review Panels → Review Procedures (Scoring, Study Section Protocol) → Summary Statements

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The Application Trail*

Receipt & Referral → Administrative Review → Peer Review → Council Review → Funding Decisions

*Not the one that leads to Argentina

Receipt and Referral

- Your application is reviewed very briefly by a Referral Officer
- Assigned to the appropriate study section (e.g., LCOM) and institute (e.g., NIDCD), based on:
  1. Program Announcement
  2. Cover Letter (included optionally)
  3. Specific Aims

Stage I: Administrative Review

- Assignment
  - Appropriate to NIH
  - Appropriate to Institute
  - Appropriate to Panel

- Compliance
  - PI eligibility
  - Application is responsive to Program Announcement
  - Application observes submission guidelines (format, application components, deadlines)
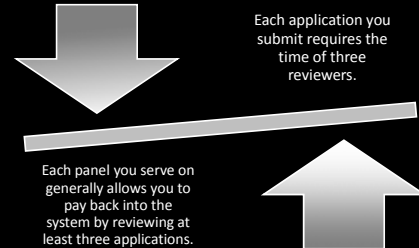

Stage II: Peer Review

- More to follow…

Stage III: Council Review

$ Funding Decisions are made in council review

Deposits & Withdrawals
at the
Review Bank & Trust

Each application you submit requires the time of three reviewers.

Each panel you serve on generally allows you to pay back into the system by reviewing at least three applications.

Reviewers

- Recognized authorities in their fields
- Principal Investigators on projects comparable to those being reviewed
- Represent the national diversity with respect to:
  - geographic distribution
  - gender
  - race
  - ethnicity

Center for Scientific Review
Panels

Examples:
(see http://www.csr.nih.gov)

AUD	Auditory System	LYNN LUETHKE
LCOM	Language and Communication	WEIJIA NI
MFSR	Motor Function, Speech and Rehabilitation	BIAO TIAN

MFSR

- normal and disordered motor function, including speech and voice production. across the lifespan, in humans and other animals.
- development and evaluation of behavioral preventive and therapeutic interventions for movement, speech, voice, and related disorders.
- Methods include behavioral experiments, physiological measurement, acoustic analysis, structural and functional imaging, and computational modeling.
- Movement: Control of limbs and extremities; body posture and balance; locomotion; head, jaw, mouth, laryngeal, eye, facial and related movements; sensory-motor integration; perception – action; motor learning and motor skills; swallowing; movement disorders.
- Sound production: Motor and perceptual aspects of production of speech and other sounds via respiratory, laryngeal, and articulatory mechanisms; interactions of motor, acoustic and perceptual aspects of sound production; relations with breathing, chewing, swallowing …
- Normal and abnormal development of movement and sound production
- Prevention and treatment of movement, speech, voice, and related disorders/disabilities; physical rehabilitation following disease or injury; prosthetic and adaptive technologies; related exercise.

AUD

- Structure and function of the auditory and vestibular systems, including:
  - Auditory system/hearing: anatomy, physiology, pharmacology, development, maturation, plasticity, disorders, the diagnosis and treatment of auditory disorders, and device assessment using approaches ranging from molecular/cellular to systems/whole organism.
  - Vestibular system/end organ: anatomy, physiology, pharmacology, development, maturation, plasticity, and neuro-otological disorders using approaches ranging from molecular/cellular to systems/whole organism.

LCOM

- Language and other types of across the lifespan, primarily in humans. All forms of language and communication, both normal and disordered, are considered.
- Perception and production of language: spoken, written, gestural, and tactile; phonetic, phonological, morphological, lexical, and syntactic analysis…
- Language development: Acquisition of first and second language, language change in adulthood; literacy development, bilingualism and multilingualism; sign language; language decline.
- Perceptual and cognitive processes underlying reading and writing abilities; acquisition and development, fluency, instructional methods, interventions for reading and writing disorders.
- Non-linguistic communication: Facial, manual, and bodily gestures; vocal, pictorial
- Neurobiological and genetic foundations underlying language and communication abilities
- Nature, origins, developmental course, assessment, prevention, treatment and remediation of language and communication disorders …
- Relations between language and thought; social roles and norms on use of language and other forms of communication; social-cultural influences of assessment and interventions for language and communication disorders.

Institute Panels

Communication Disorders Review Committee of NIDCD

Special Emphasis Panels (SEP)
R03, Requests for Proposals (RFPs), T32, P30, and others

(See http://www.nidcd.nih.gov)

Evaluation

Pre-meeting Review Procedures

- Consider and re-consider Conflicts of Interest
- All three assigned reviewers submit complete critiques, Criterion Scores, and **Preliminary Scores** online **without consultation**
- Read and consider each others' critiques over several days prior to the meeting
- Consider streamlining list
- Prepare for discussion at meeting

Other Considerations

- Confidentiality of Proceedings
  - No discussion outside meeting with others or with each other
  - Discard all materials (including your reviews)
- Conflicts of Interest
- Alleged violations of research integrity and scientific misconduct
- Consideration of streamlined applications

Streamlining

- Discussion of only those applications with a reasonable probability of being funded
- Allows greater depth in discussions of applications for which there is disagreement
- Streamlined applications receive full written feedback, Criterion Scores, and Impact Score
- Discussed applications receive, in addition, a Summary of Discussion

Scoring

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

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

Procedures for Review
Meeting Protocol

1. Having considered each others' critiques, and relying on their own specific expertise and experience, reviewers give **reconsidered** Impact Scores

Video available

2. Discussion of CORE Criteria

- Significance
- Investigator
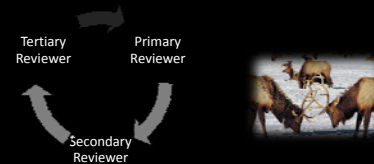- Innovation
- Approach
- Environment

Criteria Vary by Mechanism

Procedures for Review
Meeting Protocol

1. Reviewers give reconsidered Impact Scores (1-9)
2. Discussion of CORE Criteria (each receiving a score) by assigned reviewers

3. Discussion among assigned reviewers

Tertiary Reviewer   Primary Reviewer

Secondary Reviewer

Procedures for Review
Meeting Protocol

1. Reviewers give reconsidered Impact Scores (1-9)
2. Discussion of CORE Criteria (each receiving a score) by assigned reviewers
3. Discussion among assigned reviewers

4. Discussion by general panel

Procedures for Review
Meeting Protocol

1. Reviewers give reconsidered Impact Scores (1-9)
2. Discussion of CORE Criteria (each receiving a score) by assigned reviewers
3. Discussion among assigned reviewers
4. Discussion by general panel

5. Consideration of
   - Human Subjects
   - Vertebrate Animals
   - Biohazards
   - Resubmission/Renewal/Revision
     (numeric scores not assigned,
     but may be considered in Impact Score)

Procedures for Review
Meeting Protocol

1. Reviewers give reconsidered Impact Scores (1-9)
2. Discussion of CORE Criteria
3. Discussion among assigned reviewers
4. Discussion by general panel
5. Consideration of Human Subjects, Vertebrate Animals, Biohazards, Resubmission/Renewal/Revision

6. Final Impact Score recommendation by assigned reviewers
   - Whole panel votes – any vote outside recommended range requires comment

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Procedures for Review
Meeting Protocol

1. Reviewers give reconsidered Impact Scores (1-9)
2. Discussion of CORE Criteria
3. Discussion among assigned reviewers
4. Discussion by general panel
5. Consideration of Human Subjects, Vertebrate Animals, Biohazards, Resubmission/Renewal/Revision
6. Final Impact Score recommendation by assigned reviewers

7. Consideration of
   - Budget/Period of Support
   - Select Agents
   - Foreign Organizations
   - Resource Sharing Plan

Administrative Considerations. Not considered in Impact Score

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Overall Impact – Score 1-9

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.

Calculation of Impact Score

$$\overline{Score} \times 10 = \text{Final reported Impact Score}$$

- Overall impact/priority scores of discussed applications will be the average 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 (even those that are not discussed) will include the criterion scores and critiques posted by assigned reviewers

Core Review Criteria

- Five review criteria yield an overall determination of scientific and technical merit, each is scored separately.
- An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that is not innovative may be essential to advance a field.

Criterion 1: Significance

- Does the project address an important problem or a critical barrier to progress in the field?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Criterion 2: Investigator(s)

- Are the PD/PIs, collaborators, and other researchers well suited to the project?
- If Early Stage Investigators or New Investigators, do they have appropriate experience and training?
- If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
- If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Special PI Cases

- **New Investigator:** An NIH PI who has not yet competed successfully for a substantial, competing NIH research grant (e.g., an R01) is considered a New Investigator.
  - A PI who has received a Small Grant (R03) or a Developmental Research Grant Award (R21) retains status as a New Investigator.
- **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)
- **Extension of ESI Eligibility:** The 10 year period may be extended to accommodate special circumstances including medical concerns, disability, family care responsibilities, or military service.

Criterion 3: Innovation

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Criterion 4: Approach

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Criterion 5: Environment

- Will the scientific environment in which the work will be done contribute to the probability of success?
- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Criteria to be considered in Assigning an Impact Score

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards
- Resubmission Applications. Responsiveness
- Renewal Applications. Progress on last grant.
- Revision Applications. Need for supplemental funds

Protections for Human Subjects

1. Are human subjects involved?

Protections for Human Subjects

1. Are human subjects involved?
2. Are human subjects protected from research risks (ALL FOUR points must be addressed):
   1. Risks to subjects, including the likelihood and seriousness of potential risk
   2. Adequacy of protection against risks
   3. Potential benefit of the proposed research to the subjects and others
   4. Importance of the knowledge to be gained

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3. Does research meet the criteria for an exemption?

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6. Why are the sample inclusion plans scientifically acceptable or not?

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5. Are the gender and minority characteristics of the sample and the inclusion of children scientifically acceptable?
6. Why are the sample inclusion plans scientifically acceptable or not?

7. Assign codes summarizing the inclusion and acceptability status.

Inclusion of Children, Women, and Minorities

GENDER CODE: G
Second character:
1 = Both genders
2 = Only women
3 = Only men
4 = Gender unknown

Third character:
A = Scientifically acceptable
U = Scientifically unacceptable

MINORITY CODE: M
Second character:
1 = Minority and nonminority
2 = Only minority
3 = Only nonminority
4 = Minority representation unknown

CHILDREN CODE: C
Second character:
1 = Children and adults
2 = Only children
3 = No children included
4 = Representation of children is u

Examples:
G1A = Both genders, scientifically acceptable
M3U = Only nonminorities, scientifically unacceptable
C2A = Only children, scientifically acceptable

Vertebrate Animals
Checklist

1. Description of animals and their use

- Species
- Strain
- Ages
- Sex
- Number of Animals
- Procedures

Vertebrate Animals
Checklist

1. Description of animals and their use

2. Justification for:

- Use of Animals
- Choice of Species
- Number of Animals

Vertebrate Animals
Checklist

1. **Description of animals and their use:**
   Species, Strain, Ages, Sex, Number of animals, procedures
2. **Justification for:** use of animals, Choice of species, Number of animals

3. Veterinary care:

- Availability
- Frequency
- Anesthesia and recovery monitoring
- Indicators for veterinary intervention

Vertebrate Animals
Checklist

1. **Description of animals and their use:**
2. **Justification for:** use of animals, Choice of species, Number of animals
3. **Veterinary care**
4. **Provisions to minimize discomfort, distress, pain and injury:**
   - Circumstances when discomfort, distress, pain or injury may occur
   - Tranquilizers, analgesics, anesthetics, and treatments
   - Care, monitoring, or housing following surgery
   - Anesthesia, post-surgical analgesia and other treatments
   - Indicators of humane endpoints
   - restraint devices

Vertebrate Animals
Checklist

1. **Description of animals and their use**
2. **Justification for:** use of animals, Choice of species, Number of animals
3. **Veterinary care**
4. **Provisions to minimize discomfort, distress, pain and injury**
5. **Euthanasia:**
   - Method(s) for euthanasia, consistent with AVMA Guidelines on Euthanasia

Additional Factors – not influencing the Impact Score

- Budget and Period of Support
- Select Agent Research
- Applications from Foreign Organizations
- Resource Sharing Plan
  - Data Sharing Plan (DC > $500k)
  - Sharing Model Organisms
  - Genome Wide Association Studies (GWAS)

Budget

General Budget Review Information
The reviewer should determine whether the requested budget is realistic for the conduct of the proposed research.

- **MODULAR GRANTS**
- **NONMODULAR BUDGETS**
- **JUSTIFICATION FOR REDUCTIONS IN TIME OR AMOUNT OF BUDGET**
- **OVERLAP WITH OTHER SUPPORT**

Summary of Discussion

- Written by Primary Reviewer to reflect panel discussion that most influenced the Impact Score.
  - Mechanism
  - Period of support
  - Strengths contributing to Impact Score
  - Weaknesses contributing to Impact Score

Who Reads Summary Statements?

- Applicants
- Program Officers
- Grants Management Officers
- Subsequent Reviewers
- Council Members
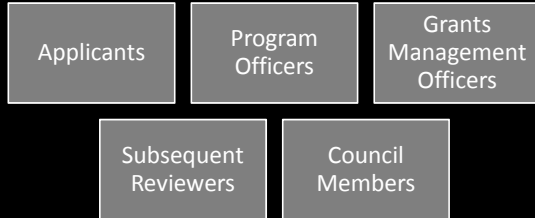
Observations about NIH Proposals

Primarily based on notes from Grant Review Training/Workshop
Scott Thomson, 18 Aug 2009

Proposed Work

- It is not just sufficient to determine whether the proposal is technically sound. Ask, "Where will this take the science?"

- Recognize that there are an infinite number of questions that can be asked. Not all of them deserve to be funded with taxpayer money.

- Potential problems if AIMS are dependent (or seen as dependent) on each other.

- Example 1: Great proposal, great investigator, but proposal did not convince reviewers that proposed work would lead to clinical advances.

- Example 2: "His tool became his hammer and the world became his nail."

Expertise

- Consultants: If researcher does not have expertise in an area, but brings in consultants, this will favorably impact quality of work done.

- Collaborators: When applicant includes collaborators, needs to be evidence that these persons have collaborated and solved issues of this nature previously.

- Qualifications of investigator – track record, productivity from previous grant considered, generally evaluated relative to stage in career.

- In NIH reviews, seeing non-peer reviewed publications in the biosketch is bad for the applicants. It is seen as padding. The same goes for listing grants held by other people; for example, grants the applicant was trained under as a student or served as an RA for should not be listed as past support.

Review Process

- Reviewers often advocate for their fields, but see following bullet.

- Why does everyone vote on every grant? This provides a system of checks that keeps people honest. Reviewers ask for clarification to help decide on what score should be if they think (1) the reviewers' comments don't fit the scores, or (2) they don't understand why something is or is not a major concern.

- The idea vs. the methods: NIH is increasingly emphasizing the former in reviews, but the money pays for the latter to be executed. Therefore a balance is needed.

- A strong primary can carry the day. A negative primary can squash a grant. So primaries set the tone.

Budget

- When does a budget issue influence the final impact score?

    o When it detracts from the environment score (e.g., evidence of lack of institutional support).

    o When it suggests too little contribution from key personnel.

- Budget issues that are administrative considerations (issues raised by reviewers, but don't influence impact score):

    o Over-budgeting for specific items.

    o Budgeting for things not mentioned in the research plan.

    o Under-budgeting for necessary items that are not already available (e.g. consumables).

After Peer Review

- Mid-range scores may be fundable but are somewhat inviting towards a revision. Very low scores are communicating that the grant has such major problems it should probably not come back in anything close to the current conceptualization.

- Be persistent. Don't bail in the face of a bad review.

- Example 1: Proposal went unscored twice, but was scored the third time.

- Example 2: Grant awarded on appeal to advisory council after peer review. Letter written to council, pre-screened by the Program Official for tone, etc. (See http://www.grants.nih.gov/grants/guide/notice-files/not97-232.html).

- The worse the score (e.g., 8-9), the more substantial the revision needs to be.

Cover Letter – Assignment to Study Section

The following is directly from Center for Scientific Review website (http://cms.csr.nih.gov/):

- Include suggestions regarding the Institutes or Centers that are most likely to be interested in the scientific area being studied; if the investigator has discussed the application with a specific program director, this information should be included.

- Include suggestions regarding the review of the application at the IRG level, the study section level, and/or a list of the scientific areas that are critical to understanding the application. For multidisciplinary applications it is very helpful for the investigator to highlight the main disciplinary or methodological thrust of the application.

- It is not appropriate to include a list of potential reviewers by name.

- It is appropriate to mention individuals by name with whom there is a conflict of interest and who should not be considered as reviewers.

- Applicants may wish to contact SROs (Scientific Review Officers) or the DRR (Division of Receipt & Referral; 301-435-0715) with specific questions about a potential assignment.

Scoring System and Procedure

EXECUTIVE SUMMARY

- The NIH grant application scoring system uses a 9-point rating for the impact/priority score with 1 = Exceptional and 9 = Poor.

- Ratings are in whole numbers only (no decimal ratings).

- Assigned reviewers also provide ratings for each review criterion [e.g. Significance, Investigator(s), Innovation, Approach, Environment] using the same 9-point scale.

  o These criterion ratings are provided in the summary statement for applications, both discussed and not discussed.

  o Criterion ratings should be considered in determining the overall impact/priority score, but reviewers should determine the relative importance of each criterion for the science or work being proposed.

- Reviewers should use the full range of the rating scale and spread their scores to better discriminate among applications.

- Discussed applications will receive impact/priority scores from all eligible reviewers (e.g., without conflicts of interest). Individual reviewer scores will be averaged and the result multiplied by 10 to determine the final impact/priority score (range of 10 to 90).

- Scores will be percentiled to the appropriate base (e.g. study section base if the number of R01 applications ≥25; CSR-all or IC-all base if <25) and reported in whole number percentiles. Until a base has been established from three rounds of review (May 2010 Council), percentiles are based on less than 3 application rounds.

- For information about using the critique template, see Critique Template Instructions.

PROCEDURE FOR PRELIMINARY SCORES

In scoring each of the core criteria and impact/priority, reviewers will use a scale of whole numbers, ranging from 1 to 9 (1= exceptional; 9= poor). The SRO will provide additional guidance on the use of this scoring scale.

Before the review meeting, determine a separate score for each of the core review criteria and a score for the impact/priority. The impact/priority score should reflect your overall evaluation rather than a weighted average applied to scores given to each criterion. An application does not need to be strong in all categories to be judged likely to have major impact. For example, a project that by its nature is not innovative may be essential to advance a field.

- The criterion scores for the applications should be entered in the meeting Internet Assisted Review (IAR) site in NIH Commons before the review meeting using the same page that is used for submitting the preliminary impact/priority score and critique. Core criterion scores can be submitted only after your critique had been uploaded into IAR.

- You must enter the criterion scores into IAR for them to appear in the summary statement. If entered in IAR, the scores will be transferred to a table at the beginning of your critique.

- Assigned reviewers may submit criterion scores only after their critiques have been uploaded. At the SRO's discretion, discussants who are assigned to the application and SRG members who are not assigned to the application may submit criterion scores without critiques.

- In the READ phase of the meeting reviewers may submit their scores and critiques, but may not edit them.

- The criterion scores should be changed during FINAL SCORING on your electronic or paper Voter/Scoring Sheet, or following the review meeting during the EDIT phase if your opinion changed as a result of discussion.

- Each core review criterion should be given a score using the nine-point rating scale in accordance with the Enhanced Peer Review Criteria.

The NIH Grant Application Scoring System

The NIH scoring system uses a 9-point rating scale from 1 = Exceptional to 9 = Poor for the overall impact/priority score as well as the individual review criteria. Ratings are provided only in whole numbers, not decimals.

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

- For the impact/priority score, the far left column provides guidance for assigning scores to applications based on the project's likelihood to have a sustained, powerful influence on the research field(s) involved:

  1 to 3 = high impact
  4 to 6 = moderate impact
  7 to 9 = low impact

- For the impact/priority score and for the individual criterion scores, the far right column provides a descriptive guide of how strengths and weaknesses are considered in assigning a rating. A score of 1 indicates an exceptionally strong application (or exceptionally strong significance, investigators, innovation, approach, environment) with essentially no weaknesses. A score of 9 indicates serious and substantive weaknesses with very few strengths. For the impact/priority score rating, strengths and weaknesses across all of the review criteria should be considered. For each criterion rating, the strengths and weaknesses within that review criterion should be considered.

- Reviewers should consider not only the relative number of strengths and weaknesses noted, but also the importance of these strengths and weaknesses to the criteria or to the overall impact when determining a score. For example, a major strength may outweigh many minor and correctable weaknesses.

Not Discussed and Not Recommended for Further Consideration

Applications judged unanimously by the peer reviewers as less competitive, based on preliminary impact/priority scores (roughly the bottom half of applications for that review meeting), will not be discussed and will not receive a final impact/priority score. Although the summary statement for such an application will indicate "ND" (not discussed), it will contain critiques and criteria scores from each of the assigned reviewers.

An application may be designated Not Recommended for Further Consideration (NRFC) by the Scientific Review Group if it: lacks significant and substantial merit; presents serious ethical problems in the protection of human subjects from research risks; or presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents. Applications designated as NRFC do not proceed to the second level of peer review (National Advisory Council/Board) because they cannot be funded.

Following discussion, however, reviewers should feel free to assign the score that they believe best represents the impact of the application, and not feel constrained to limit their score to the upper half of the score range if they do not feel such a score is justified. For example, if the assigned reviewers initially score an application as 4, 5, and 6, and subsequent discussion reveals a serious weakness that will substantially lessen the project's impact, then it is appropriate for reviewers to give a higher (worse) score.

Distribution of Scores

With 9 possible rating discriminations, it is imperative that reviewers distribute or spread their scores as widely as possible among applications. The descriptors associated with each rating were designed to encourage the spreading of scores. Therefore, although score distributions may vary by study section, reviewers should use the full range of 1 to 9; the expectation, however, is that there will be few 1s and few 9s.

This scoring system was designed to encourage greater spreading of scores. Highly rating all applications greatly diminishes the ability of a reviewer or study section to communicate the

impact of an application. Therefore, reviewers who carefully consider the rating guidance provided in determining their scores improve not only the reliability of their scores, but also improve their ability to communicate the impact of the applications reviewed.

Scoring Range

After discussion, the assigned reviewers state their final scores, defining the score range. Based on the discussion, all eligible reviewers also score the application. If reviewers wish to score outside the score range of the assigned reviewers, they should declare that they intend to score outside the range and briefly describe the reason. Any score outside the range of the assigned reviewers should be declared, even if the range is a single score (i.e. all assigned reviewers give the same final score). It is important that all points of view and opinions of reviewers are discussed; therefore, reviewers should feel free to score outside the range based on their determination of the overall impact of the application.

All scientific opinions concerning an application that is discussed at the SRG meeting should be raised during that discussion. Therefore, SRG members whose evaluations or opinions of an application fall outside the range of those presented by the assigned reviewers and discussant(s) should ensure that their opinions are brought to the attention of the entire committee. In addition, the SRO and Chairperson should ensure that all opinions are voiced before final scoring is conducted.

Additional Guidance on Criterion Scoring

Assigned reviewers provide both preliminary impact/priority scores and criterion scores (ratings of each review criteria). These criterion scores are included in the summary statement to give applicants of both discussed and not discussed (i.e. streamlined) applications a sense of how consideration of the review criteria influenced the overall evaluation of the application. However, because the relative importance of each individual criterion to the overall score differs for each application, reviewers should not use a formula of weighted or unweighted averages across applications to determine the overall impact/priority score. In addition, unrated criteria such as human subjects, vertebrate animal care, and RFA-specific criteria also should be considered in determining the overall impact/priority score. Therefore, each review criterion should be weighed differently for each application depending on how important each review criterion is to the work being proposed. As a result, a reviewer may give only moderate scores to some of the review criteria but still give a high overall impact/priority score because the one review criterion critically important to the research is rated highly; or a reviewer could give mostly high criterion ratings but rate the overall impact/priority score lower because the one criterion critically important to the research being proposed is not highly rated.

Final Impact/Priority Scores and Percentile Scores

Discussed applications will receive impact/priority scores from all eligible reviewers. Individual reviewer scores will be averaged and the result multiplied by 10 to determine the final impact/priority score (range of 10 to 90) reported in the summary statement.

Scores will be percentiled to the appropriate base (e.g. study section base if the number of R01 applications ≥25; CSR-all or IC-all base if <25) and reported in whole number percentiles. Until a base has been established from three rounds of review (May 2010 Council), percentiles are based on less than 3 application rounds.

Insider's Guide to Peer Review For Applicants

NIH Center for Scientific Review

To help new and established applicants submit better applications, CSR asked six current and retired study section chairs to share their personal insights on what makes a good NIH grant application. They responded with great enthusiasm. We present some of their responses in their own words to preserve their sprit and impact. Applicants are encouraged to consider the additional tips and official application guidelines on the NIH Web site: **http://grants.nih.gov/grants/grant_tips.htm.**

Propose something significant: It is a real turn-off to read an application that is basically a re-hash of a previous project with a new tissue. The same goes for "me too" research. Identify an area of current controversy and importance within your field. Make it something that would interest more people than you and your coworkers. Will it be important to clinicians or other investigators? Are you dealing with key questions or controversies in the field?

Good ideas don't always sell themselves: Tell me why it's important up front in the background section, and I'll be ready to roll. Tell me what's known and what isn't known and how, after you complete your studies, you'll move the field forward or answer important questions. A lot of people really are unaware of how absolutely important it is to tell the reviewer from the beginning why it's worth doing. If you're seeking an incremental advance over what's known, it's essential to justify it.

Make it exciting: I love to see fresh, well-supported ideas that have a good hypothesis behind them that could really open up an area. And I find it both exciting and intellectually stimulating to encounter new approaches to major problems and research that could advance both clinical and basic science. Even if it's somewhat high risk, if it comes with a good hypothesis and you can test it, I'd find it very exciting.

Probe for mechanisms and seek new models. We need to know how something happens—not just what happens. With this knowledge we can affect outcomes and design something to prevent something from happening. If you don't know what's happening on the bench, you're not going to move to the bedside with any reproducible or knowledgeable treatment.

If you really want to know how to write a good application, serve on a study section.

Rozanne M. Sandri-Goldin
University of California, Irvine

Avoid proposing to "collect more data." It might help you to set up the system, but if it is not critical to fundamental understanding do not dwell on it. Although some experiments might take a lot of time to perform, they will not necessarily qualify as specific aims.

Be very clear and very concise about what you want to do, why it's important, and what you expect to get out of it. Keeping it clear doesn't mean doing away with complexity. Just make sure your general sense and key questions come across very clearly *throughout* your proposal.

Don't assume too much: Not all reviewers will have the same in-depth, highly expert, knowledge you do. Avoid any unnecessary technical jargon, and write your application assuming it will be reviewed by intelligent scientists who have a breadth of knowledge around your area. So consider getting a researcher at your institution who isn't an expert in your field to read your application and tell you how well it flows.

Be brief with stuff everyone knows: Lots of people go too far describing routine laboratory methods, which just take up space and really distract reviewers. It gives the message that the

applicant is not really as organized as they should be. New investigators, however, should make a little more effort to show that the techniques they proposed to use are within their capabilities.

Aim each aim: Spend time on the Expected Outcomes, Data Interpretation, Pitfalls, and Contingencies section for each aim. The "expected outcomes" section shows you've got a logical strategy. The section on Data Interpretation gives insight into your depth of understanding the problem. The Pitfalls section shows how familiar you are with the proposed techniques and methodologies. Finally, in discussing alternative strategies, you can give us confidence you are able to deal with the problems that arise when experiments don't work as expected.

Pull it together: At the end of your methods section, have a succinct, one paragraph summary of what you intend to do, how you intend to do it and what it is going to tell you. Write it like a manuscript abstract. After reading 25 pages, I've gotten into a lot of experimental details, and it is really helpful at the very end if I can get the take home message.

Don't jump too fast into writing your application, particularly if you're a new applicant. The most critical parts are the summary and specific aims sections. So write a one-page summary page with specific aims first and share it with someone who is experienced, has their own funding or—ideally—someone who has served on a study section. If you can't wow them, start again and use the time you saved to come up with some fresh ideas.

Don't test the waters to see how reviewers like your initial ideas or let them find the limitations for you. Find the limitations yourself and discuss them in the application.

Don't cram your application like a suitcase: At every single meeting, I hear reviewers complain about small font, tiny margins, numbered references (because they require readers to constantly flip back to the reference section) and statements such as "See the reprint in the appendix for details." I love to see spaces between paragraphs, spaces between sections, and figure legends I don't need to bring up the pdf magnification to 200x to read.

Proofread your application. Better yet, have someone else proofread it!

The key word for applicants is persistence. Half the applications reviewed are unscored [streamlined]. So don't despair. You're in good company. Go through your critiques with your investigators. If there's a fatal flaw, stand back and then decide the best route to take next time. But usually the weaknesses are fixable. Fix them and re-submit.

Get More Grant Writing Tips from NIH
   http://grants.nih.gov/grants/grant_tips.htm

Learn More About the Peer Review Process
   http://cms.csr.nih.gov/

Definitions of Criteria and Considerations for Research Project Grant (RPG/R01/R03/R15/R21) Critiques

Standard criteria and considerations are shown below. Individual Funding Opportunity Announcements (FOAs) may have different criteria and considerations

Overall Impact (for all RPG Applications). After considering all of the review criteria, briefly summarize the significant strengths and weaknesses of the application and state the likelihood of the project to exert a sustained powerful influence on the field.

Additional Guidance for R03, R15, and R21 applications:

Small Research Grant Program (R03). The R03 small grant supports discrete, well-defined projects that realistically can be completed in two years and that require limited levels of funding. Because the research project usually is limited, an R03 grant application may not contain extensive detail or discussion. Accordingly, reviewers should evaluate the conceptual framework and general approach to the problem. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or from investigator-generated data. Preliminary data are not required, particularly in applications proposing pilot or feasibility studies.

Academic Research Enhancement Award (R15). Consider as part of the overall impact whether the proposed project addresses the objectives of the AREA grant program which are to (1) provide support for meritorious research, (2) strengthen the research environment of schools that have not been major recipients of NIH support, and (3) expose available undergraduate and graduate students in such environments to meritorious research. Preliminary data are not required for R15 application; however, they may be included if available.

Exploratory/Developmental Research Grant Program (R21): The R21 exploratory/developmental grant supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Accordingly, reviewers will focus their evaluation on the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be included if available.

1. Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Additional Guidance for R01 applications:

New Investigator: An NIH research grant Program Director/Principal Investigator (PD/PI) who has not yet competed successfully for a substantial, competing NIH research grant is considered a New Investigator. For example, a PD/PI who has previously received a competing NIH R01

research grant is no longer considered a New Investigator. However, a PD/PI who has received a Small Grant (R03) or an Exploratory/Developmental Research Grant Award (R21) retains his or her status as a New Investigator. A complete definition of a New Investigator along with a list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator can be found at http://grants1.nih.gov/grants/new_investigators/resources.htm.

Early Stage Investigator (ESI): An individual who is classified as a New or First-Time Investigator and is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent) is considered an Early Stage Investigator (ESI). The 10 year period after completion of the terminal degree or residency may be extended to accommodate special circumstances including various medical concerns, disability, pressing family care responsibilities, or active duty military service. If an extension has been approved, the SRO will bring this to the reviewers' attention.

2. Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

3. Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

4. Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

5. Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Protections for Human Subjects. For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 (as described in Human Subjects Protection and Inclusion), reviewers are asked to evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. If all of the criteria are adequately addressed, and there are no concerns, write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. Also, if a clinical trial is

proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRO immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt, evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. If the claimed exemption is not justified, indicate "Unacceptable", and, if unacceptable, explain why it is unacceptable.

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate. For additional information to assist you in making these determinations, please refer to Human Subjects Protection and Inclusion and Human Subjects Worksheet for Comments.

Inclusion of Women, Minorities, and Children. When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4. Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

Gender Inclusion Code	Minority Inclusion Code	Children Inclusion Code
G1 = Both genders	**M1** = Minority and nonminority	**C1** = Children and adults
G2 = Only women	**M2** = Only minority	**C2** = Only children
G3 = Only men	**M3** = Only nonminority	**C3** = No children included
G4 = Gender composition unknown	**M4** = Minority composition unknown	**C4** = Representation of children unknown
	M5 = Only foreign subjects	

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate.
For additional information to assist you in making these determinations, please refer to Human Subjects Protection and Inclusion and Human Subjects Worksheet for Comments.

Vertebrate Animals. The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and

species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information to assist you in determining if the Vertebrate Animals section is "Acceptable" or "Unacceptable", please refer to Vertebrate Animals checklist.

Biohazards. Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission. When reviewing a Resubmission application (formerly called an amended application), the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal. When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.

Revision. When reviewing a Revision application (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident. For additional information, see http://grants.nih.gov/grants/peer/guidelines_general/Revision_Applications.pdf.

Budget and Period Support. Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. For more details, please see Budget Information.

Select Agents. Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s). For more details, please see Select Agents.

Applications from Foreign Organizations. Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources. Reviewers do not need to comment on the foreign component of domestic applications in this consideration. Comments should be included in the Approach (scored criteria #4) as applicable.

Resource Sharing Plans. Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable:

> **Data Sharing Plan**. Applications requesting more than $500,000 direct costs in any year of the proposed research are expected to include a data sharing plan in their application. Certain Program

applicant is not really as organized as they should be. New investigators, however, should make a little more effort to show that the techniques they proposed to use are within their capabilities.

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Learn More About the Peer Review Process
  http://cms.csr.nih.gov/