Slide 1: The NIH Peer Review Process

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Center for Scientific Review
National Institutes of Health
U.S. Department of Health and Human Services

Slide 2: National Institutes of Health Organizations

Office of the Director

- National Institute on Alcohol Abuse and Alcoholism
- National Institute of Arthritis and Musculoskeletal and Skin Diseases
- National Cancer Institute
- National Institute on Drug Abuse
- National Institute of Environmental Health Sciences
- National Institute on Aging
- National Institute of Child Health and Human
- Development National Institute on Deafness and Other Communication Disorders
- National Eye Institute
- National Human Genome Research Institute
- National Institute of Mental Health
- National Institute of Neurological Disorders and Stroke
- National Institute of General Medical Sciences
- National Institute of Nursing Research
- National Library of Medicine
- National Center for Complementary and Alternative Medicine
- National Institute of Allergy and Infectious Diseases
- Fogarty International Center
- National Center for Research Resources
- National Center on Minority Health and Health Disparities
- National Institute of Biomedical Imaging and Bioengineering

- National Heart, Lung, and Blood Institute
- National Institute of Dental and Craniofacial Research
- National Institute of Diabetes and Digestive and Kidney Diseases
- Clinical Center
- Center for Information Technology
- Center for Scientific Review

Slide 3: 24 NIH Institutes and Centers Fund Grants

NCI Center for Scientific Review

1. NIGMS
2. NIA
3. NIAAA
4. NEI
5. NIAMS
6. NIMH
7. NHLBI
8. NHGRI
9. NICHD
10. NIDDK
11. NIDA
12. NINDS
13. NIAID
14. NIDCR
15. NINR
16. NIEHS
17. NIDCD
18. NLM
19. NCRR
20. FIC
21. NCCAM
22. NIBIB
23. NCMHD

Slide 4: CSR Referral

Applications Are Assigned to:

- Scientific Review Groups for review based on:
    - Specific referral guidelines for each scientific review group
- NIH Institutes or Centers for funding based on:
    - Overall mission of the Institute or Center
        - Referral guidelines for each funding IC

- Specific programmatic mandates and interests of the Institute or Center

Slide 5: CSR Peer Review – Fiscal Year 2010

- 88,000 applications received
- 61,000 applications reviewed
- 18,000 reviewers
- 240 Scientific Review Officers
- 1,600 review meetings

Slide 6: Where are Applications Reviewed?

- CSR
  - Research Projects
  - Academic Research
  - Enhancement Awards
  - SBIR & STTR
  - Shared Instrumentation
  - Career Awards
  - Small Grants
  - Fellowships
  - RFAs
- Institutes/Centers
  - Contracts
  - Program Projects (most)
  - Institutional Training Grants
  - Conference Grants
  - Centers
  - Career Awards
  - Small Grants
  - Fellowships
  - RFAs

Slide 7: CSR: Divisions and Integrated Review Groups (IRGs)

- Neuroscience, Development and Aging
  - Brain Disorders & Clinical Neuroscience
  - Molecular, Cellular & Developmental Neuroscience
  - Integrative, Functional & Cognitive Neuroscience
  - Emerging Technologies & Training in Neuroscience
  - Biology of Development & Aging
- AIDS, Behavioral and Population Sciences
  - Biobehavioral & Behavioral Processes
  - Risk, Prevention & Health Behavior
  - Population Sciences & Epidemiology
  - Healthcare Delivery & Methodologies
  - AIDS & AIDS Related Research
- Basic and Integrative Biological Sciences
  - Biological Chemistry & Macromolecular Biophysics
  - Bioengineering Sciences & Technologies
  - Cell Biology
  - Genes, Genomes & Genetics
  - Oncology: Basic Translational
  - Interdisciplinary Molecular Sciences & Training
- Physiological and Pathological Sciences
  - Endocrinology, Metabolism, Nutrition & Reproductive Sciences
- Translational and Clinical Sciences
  - Cardiovascular and Respiratory Sciences
  - Immunology Infectious Diseases & Microbiology
  - Digestive, Kidney & Urological Systems
  - Surgical Sciences, Biomedical Imaging and Bioengineering
  - Musculoskeletal, Oral & Skin Sciences
  - Oncology: Translational Clinical
  - Vascular and Hematology

Slide 8: Division of AIDS, Behavioral and Population Sciences

- Biobehavioral & Behavioral Processes
- Risk, Prevention & Health Behavior
- Population Sciences and Epidemiology
  - Social Sciences and Population Studies
  - Behavioral Genetics and Epidemiology
  - Cardiovascular and Sleep Epidemiology
  - Epidemiology of Cancer
  - Kidney, Nutrition, Obesity, & Diabetes Epidemiology
  - Infectious Diseases, Reproductive Health, Asthma and Pulmonary Epidemiology
  - Neurological, Aging and Musculoskeletal Epidemiology

- Healthcare Delivery and Methodologies
- AIDS and Related Research

Slide 9: Division of AIDS, Behavioral and Population Sciences

- Biobehavioral & Behavioral Processes
- Risk, Prevention & Health Behavior
- Population Sciences and Epidemiology
- Healthcare Delivery & Methodologies
- Bio-statistical Methods and Research Design
    - Biomedical Computing and Health Informatics
    - Community-Level Health Promotion
    - Community Influences on Health Behavior
    - Dissemination and Implementation Research in Health
    - Health Disparities and Equity Promotion
    - Health Services Organization and Delivery
    - Nursing and Related Clinical Sciences
    - Societal and Ethical Issues in Research
- AIDS & Related Research

Slide 10: Help Your Application Get to the Right Study Section

- Review CSR Integrated Review Group and Scientific Review Group (Study Section) guidelines to identify a home for your application.
- Submit a Cover Letter!

Slide 11: Help Your Application Get to the Right Study Section

http://www.csr.nih.gov/
[image]
Center for Scientific Review web page
[end image]

Slide 12: Help Your Application Get to the Right Study Section

Integrated Review Group
[image]

Web page for Integrated Review Group,
http://public.csr.nih.gov/StudySections/IntegratedReviewGroups/Pages/default.aspx .

Purpose:
Review activities of the Center for Scientific Review (CSR) are organized into Integrated Review Groups (IRGs). Each IRG represents a cluster of study sections around a general scientific area. Applications generally are assigned first to an IRG, and then to a specific study section within that IRG for evaluation of scientific merit.
[end image]

Slide 13: Help Your Application Get to the Right Study Section

Study Section
[image]
Study Section web page, http://public.csr.nih.gov/StudySections/Pages/default.aspx.

Applications are reviewed in Study Sections. Integrated Review Groups (IRGs) are clusters of Study Sections based on scientific discipline.
[End Image]

Slide 14: Cover Letter

The cover letter should be used for a number of
important purposes:

- Suggest Institute/Center assignment
- Suggest review assignment
- Identify individuals in potential conflict and explain why
- Identify areas of expertise needed to evaluate the application
- Discuss any special situations

It is NOT appropriate to use the cover letter to suggest specific reviewers.

Slide 15: Sample Cover Letter

Please assign this application “Immunology of Kidney Transplant
Rejection” to the following:

- Institutes/Centers
    - National Institute of Diabetes, Digestive and Kidney Diseases (primary)

    - National Institute of Allergy and Infectious Diseases (dual)
- Scientific Review Group
    - Digestive, Kidney, and Urological Systems

Please do not assign this application to the following:

- Scientific Review Group
    - Immunology IRG

This study focuses on improving outcomes specifically for kidney transplant, not general immunological aspects.

Slide 16: Review Process for a Research Grant

Comes from Research Grant Application and School or Other Research Center

The following it the flow process:

- Initiates Research Idea
- Submit Application to
- National Institutes of Health
    - Center for Scientific Review
        - Assigns to I C & I R G/Study Section
    - Study Section
        - Reviews for Scientific Merit
    - Institute
        - Evaluates for Relevance
    - Advisory Councils and Boards
        - Recommends Action
    - Institute Director
        - Take Final Action
- Allocates Funds
- Conduct research

Slide 17: Core Review Criteria for R01 Applications

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?

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?

Slide 18: Core Review Criteria for R01 Applications

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?

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?

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?

Slide 19: Additional Criteria

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

Revision Applications. (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the

Slide 20: Scientific Review Process

Dual Review System for Grant Applications

- First Level of Review CSR or Institute Review
  - Scientific Review Group (Study Section)
- Second Level of Review
  - NIH Institute/Center Council

Slide 21: CSR Study Sections

- Each CSR standing study section has 1228 regular members who are primarily from academia
- Ad Hoc members • CSR standing study sections convene face-to-face meetings
- As many as 60-100 applications are reviewed by each study section

Section 22: Criteria for Selection of Peer Reviewers

- Active and productive researchers
- Demonstrated scientific expertise
- Mature and impartial judgment
- Work effectively in a group context
- Breadth of perspective
- Interest in serving
- Diversity of gender, ethnicity and geography

Slide 23: Where Do We Find Reviewers?

- CSR Registry for Volunteer Reviewers
- Successful applicants
- Recommendations from reviewers and NIH staff • N I H Reporter (http://projectreporter.nih.gov/reporter.cfm)
- Internet
- Scientific conferences

Slide 24: Pre-Meeting Activities -Reviewers

- Reviewers receive applications and assignments 6-8 weeks prior to meeting
  - Identify conflicts of interest
  - Generally assigned between 8-12 applications

    - Write critiques prior to the meeting
- Post preliminary scores and critiques on secure meeting website
- Read written critiques of other reviewers a few days before the meeting

Slide 25: What Happens at the Study Section Meeting

- Closed Meeting
    - Orientation
    - Conflict of Interest
    - Confidentiality
    - Developments of interest to the study section
    - Changes in policy or procedure
    - Roles of the persons present
        - Chair and other Reviewers
        - Program Officers (Observers)
        - SRO
- Application by Application review

Slide 26: Certification of No Conflict of Interest

This will certify that in the review of applications and proposals by (study section) on (date), I did not participate in the evaluation of any grant or fellowship applications from (1) any organization, institution or university system in which a financial interest exists to myself, spouse, parent, child, or collaborating investigators; (2) any organization in which I serve as officer, director, trustee, employee or collaborating investigator; or (3) any organization which I am negotiating or have any arrangements concerning prospective employment or other such associations.

[image]
SIGNATURES
Eight signature lines under signature
[end image]_____ _____

Slide 27: Confidentiality

- Review materials and proceedings of review meetings represent privileged information to be used only by reviewers and NIH staff.
- At the conclusion of each meeting, reviewers will be asked to destroy or return all review-related material.

- reviewers should not discuss review proceedings with anyone except the SRO.
- Questions concerning review proceedings should be referred to the SRO.

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Slide 28: Review of Each Application

- Reviewers with conflicts leave room
- Assigned reviewers state preliminary scores
- Discussion of scientific and technical merit
    - Based on the 5 review criteria
    - Assigned reviewers first then open discussion to whole committee
- Discussion of Protection of Human Subjects and Inclusion criteria
- Assigned reviewers state final score – range of scores is set
- Every member scores each application
- Budget and Administrative concerns
- Ideal time for each application -15 to 20 minutes

Slide 29: N I H Peer Review Revealed

View the Videos

- NIH Peer Review Revealed
- NIH Tips for Applicants

[video]
http://www.csr.nih.gov/video/video.asp
[end video]

Slide 30: Separation of Funding and Review

[image]
Silhouette of man with a briefcase and a light bulb extended
[end image]

Program Staff:

- Identify and promote research priorities
- Recommend projects for funding (based on score, budget, priorities)

- Manage portfolio of projects
- Work with applicants up to review and after review

[image]
scales with two holding bowls on each end
[end image]

Review Staff:

- Manage study section meetings to evaluate scientific and technical merit
- Provide a fair, thorough and competent review for each application
- Work with applicants before review

Slide 31: Enhancing Peer Review Background

Peer Review Process:
Diagnostic

- Year-long Deliberative Effort Gathering Feedback & Input:
  - Request for Information
  - N I H Staff Survey
  - I C White Papers
  - Internal Town Hall Meeting
  - External Consultation Meetings
  - Data analysis
  - Internal and External Working Groups

Design Implementation Plan

- Indentified Key Recommendations

Begin Phased Implementation of Selected Actions

- Per Review Oversight Committee (P R O C) Established Working Groups
  1. Engaged the Best Reviewers
  2. Improve the Quality and Transparency of Review
  3. Ensure Balance and Fair Reviews Across Scientific Field and Careed Stages
  4. Continuous Review of Peer Review

Slide 32: Outline of Changes

Timeline:

- January 2009
  - Phase out of A2 applications
  - Identification of Early Stage Investigator (E S I) R01 applications
- May/June 2009 Reviews
  - Enhanced review criteria
  - New scoring system

    - Criterion scoring
    - Structured critiques
    - Score order review
    - Clustering of New Inv. Applications
- January 25, 2010 Submissions
    - Priority Area 2 – Improve the Quality and Transparency of Review
    - Restructured Applications
    - Shorter Page Limits and New Instructions

Slide 33: Determination of New Application Status

- Expected to be substantially different in content and scope with more significant differences than are normally encountered in a resubmitted application.
    - should include substantial changes in all sections of the Research Plan, particularly in the Specific Aims and the Research Strategy sections.
    - should be fundamental changes in the questions being asked and/or the outcomes examined.
    - should produce a significant change in direction and approach for the research project.
- Rewording of the Title and Specific Aims or incorporating minor changes in response to comments of reviewers in the most recent Summary Statement does not constitute substantial changes in scope, direction or content.
- http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-080.html

Slide 34: New and Early Stage Investigators

- New Investigator (NI)
    - PD/PI who has not yet completed successfully for an R01 or other substantial NIH research grant
- Early Stage Investigator (ESI)
    - PD/PI who qualifies as a New Investigator AND is within 10 years of completing the terminal research degree or is within 10 years of completing medical residency

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

Slide 35: Enhanced Review Criteria

- Overall Impact

    - Assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved
- Core Review Criteria
    - Significance
    - Investigator(s)
    - Innovation
    - Approach
    - Environment

Review criteria each scored from 1-9

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-025.html

Slide 36: 9-Point Scoring Scale

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

Slide 37: Scoring

9-point score scale is used to provide:

- Criterion Scores for each of the 5 core review criteria
- Overall Impact/Priority Score based on, but not an average of, the core criterion scores plus additional criteria

All applications receive scores:

- Not discussed applications will receive only initial criterion scores from the three assigned reviewers.
- Discussed applications also receive an averaged overall impact score from eligible (i.e., without conflicts of interest) panel members.

Slide 38: Excerpt from a Critique Template

[image]
partial template from Critique template. It is in table format and begins with 1. Significance. Under that column it begins with 'Strengths' and goes down through 'Weaknesses'. The next, and last, column is a place to put in remarks. It asks you to limit text to 1/4 page.
[end image]

List major strengths and weaknesses that influenced the overall impact/priority score

Slide 39: Restructured Applications

Goal: Align structure and content of applications with Review criteria and improve efficiency and transparency of the review process

- Application forms revised in three sections:
  - Research Plan
  - Biographical Sketch
  - Resources and Facilities
- Shorter page limits implemented for many programs

Slide 40: Alignment

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

Slide 41: Shorter Page Limit Guide

Section of Application	Page Limits
Introduction for Resubmission Application	1
Specific Aims	1
Research Strategy: R03, R13/U13, R21, R36, R41, R43, Fellowships (F), SC2, SC3	6
Research Strategy: R01, single project U01, R10, R15, R18, U18, R33, R24, R34, U34, R42, R44, DP3, G08, G11, G13, UH2, UH3, SC1	12
Biographical Sketch	4

*Page limits may vary for other funding mechanisms. Check Funding Opportunity Announcement: http://enhancing-peer-review.nih.gov/page_limits.html

Slide 42: NIH Peer Review Information on the Web

National Institutes of Health: http://www.nih.gov

- Office of Extramural Research: http://www.nih.gov/grants/oer.htm
- Grants Policy: http://www.nih.gov/grants/policy/policy.htm
- Electronic Submission: http://era.nih.gov/ElectronicReceipt
- Review Criteria at a Glance: http://grants.nih.gov/grants/peer/guidelines_general/Review_Criteria_at_a_glance.pdf

Center for Scientific Review: http://www.csr.nih.gov

- Resources for Applicants: http://www.csr.nih.gov/ResourcesforApplicants
- CSR Study Section Rosters: http://www.csr.nih.gov/committees/rosterindex.asp
- Review Group Meeting Dates: http://www.csr.nih.gov/Committees/meetings/ssmeet1.asp