NIAID Bridging the Career Gap for Under-represented Minority Scientists Workshop

NIH Grant System and Peer Review

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Topics for this Presentation

- Overview
- Extramural funding mechanisms
- Submission of grant applications and policies
- Center for Scientific Review: NIH receipt & referral system
- Peer review process
- First level of review - Scientific Review Groups
  - Peer review roles
  - Peer review criteria and considerations and scoring
  - Peer review meeting overview
- Post-review period- scores, summary statement
- Second level of review - Advisory Council/Board
- Seven habits of highly successful applicants

Topics Not Covered in this Presentation

- Finding opportunities for research funds
- Preparation of an NIH grant application
- Appendix material/overstuffed applications
- Role of Program Officials
- Role of Grants Management staff

Overview: Pursuit of Research Support

- Brings out the best science
- Encourages networking with other investigators
- Promotes discussions and collaborations with scientists worldwide whose interests overlap
- Allows mentoring of junior researchers
- Funds research that may ultimately improve the health of many
- Gives a feeling of personal satisfaction and a sense of accomplishment

Extramural Funding Mechanisms

- Training Grants (T) /Research Career Awards (K)
- Research Project Grants (R)
- Research Program Project and Center Grants (P)
- Cooperative Agreements (U)
  - Used by federal agencies to fund projects/research that require substantial involvement from agency staff
- Research and Development (R&D) Contracts (N)
  - Used by Federal agencies to secure a binding agreement between the government and the Offeror for provision of goods or services (deliverables) in return for monetary considerations in high priority scientific areas.

Grant Applications Submission Schedule

- Jan./May/Sept. 25: All Ps, Rs (not listed below), Ts
- Feb./June/Oct. 5: New R01s
- Feb./June/Oct. 12: New Ks
- Feb./June/Oct. 16: New R03, R21, R33, R21/R33, R34, R36
- Feb./June/Oct. 25: All AREA
- Mar./July/Nov. 5: Renewal, Resubmission, Revision R01s
- Mar./July/Nov. 12: Renewal, Resubmission, Revision Ks
- Mar./July/Nov. 16: Renewal, Resubmission, Revision R03, R21, R33, R21/R33, R34, R36

Grant Applications Submission Schedule (cont.)

- Apr./Aug./Dec. 5: SBIR and STTR
- Apr./Aug./Dec. 8: Fs
- Apr./Aug./Dec. 10: Resubmission New Investigator R01s
- Apr./Aug./Dec. 12: R13, U13
- Apr./Aug./Dec. 13: Diversity F31s
- May/Sept./Jan. 7: All AIDS applications - paper & electronic
- http://grants1.nih.gov/grants/funding/submissionschedule.htm
- RFAs/PARs: Each month – paper & electronic

Application Submission Policies

- Use current application forms/instructions
- All Program Director/Principal Investigator (PD/PIs) must have Commons User ID
- Institute/Center (IC) approval required for all applications requesting $500,000 or more direct costs in any year

  Applies to new, renewal, revision, and resubmission applications; inquire six weeks in advance

Application Submission Policies (cont.)

- R13/U13 applications require prior approval
- Modular Budgets for R01, R03, R15, R21, and R34/U34 at $250,000 or less (unless foreign applicant)
- All foreign applications – full budget
- Leadership Plan required for Multiple PD/PI applications.

Submission of Electronic Applications

- Start the process very early!
- Submission to Grants.gov
- NIH Exchange processing/assembly; error checking and correction
- Assembly of application

Submission of Electronic Applications (cont.)

- PD/PI and institution have two business days to check application
- Application automatically forwarded to CSR Division of Receipt and Referral (DRR)
- Access eRA Commons to obtain information on validations
- Errors must be corrected (begin at Grants.gov)

Submission of Electronic Applications (cont.)

- Optional correction for warnings; may be fixed at the applicant's discretion and do not hinder the application from moving forward
- Resubmission of the entire changed/corrected application must be through Grants.gov
- Generation of a grant image and availability to check = A successful submission
- Viewing window – first chance to see assembled application as reviewers will see it

Critical Reminders

- Don’t wait till the last minute!
- Failure to see an application image in eRA Commons, implies that the NIH does not see it either
- Follow up on the process and use eRA Commons to check
- NIH needs to know you have submitted an application in order to assign, review and award

On Time Submission- Electronic Applications

- Successful submission by 5 P.M. local time
- Weekend/holiday– next business day
- Grace period for reference letters and Error Correction Window are non-existent
- Modified applications submitted after the due date are late and will not be accepted.
- Only exception: NIH identified system errors at either Grants.gov or eRA Commons

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-123.html
http://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines

On Time Submission- Paper Applications

- Standard date = submission
- Weekend/holiday – next business day
- Special date = receipt

Submission of Multi-project Applications

- Multi-project applications- submitted by Application Submission System & Interface for Submission Tracking) ASSIST

- Guide Notice for ASSIST:

NOT-OD-13-095: Using ASSIST to Prepare and Submit Multi-Project Applications to NIH: Webinar - August 13, 2013

- Electronic Contract Proposal Submission (eCPS) site used to submit contract proposals at some ICs

- Paper grant applications/contract proposals

Exceptions for Late Applications

- Reason(s) should apply to PD/PI only
- For multi-PI applications, only one individual PI needs to have a reason
- Participation in review must be a concurrent service (not distant past)
- Approval by CSR DRR is not granted in advance
- Cover letter is required

Exceptions for Late Applications (cont.)

- Window of consideration
  - 2 weeks for standard dates
  - 1 week for expedited dates (small business, fellowship, conference, AIDS applications)
  - None for special dates (RFAs/PARs)

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html

Helpful Numbers and Websites

- General information on Electronic Research Administration: http://era.nih.gov/
- Grants.gov registration, submission and Adobe questions:
  - http://www.grants.gov/CustomerSupport
  - Email support@grants.gov
  - Phone: 1-800-518-4726
- eRA Commons registration and post submission questions on Commons functionality

  https://commons.era.nih.gov/commons/
  - eRA Commons Help Desk
    - **Web support: http://era.nih.gov/help/index.cfm#era**
    - **E-mail: commons@od.nih.gov**
    - **Phone: 1-866-504-9552 OR 301-402-7469**

Resubmission Policy

Resubmission Requirements:

- Summary Statement must be posted in eRA Commons
- Heed Summary Statement suggestions to change content of the A1 application
- One-page introduction generally required
- Only one resubmission (A1) is allowed; this must be submitted within 37 months of A0 application
- Applies to all types of applications and all activity codes

Resubmission Policy Websites

http://grants1.nih.gov/grants/guide/notice-files/not-od-09-016.html

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html

http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-080.html

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-140.html

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html

Virtual A2 Applications

- A PI with an unfunded A1 application, should not submit a “virtual A2” application
- Substantial changes must be made in Specific Aims and Approach for the next submission
- A greater change is needed than for the resubmission application; not just response to issues in Summary Statement

Virtual A2 Applications (cont.)

- A request for different review location or IC assignment is insufficient to consider an application as a new one
- Use of a different FOA is also insufficient
- Further guidance (including FAQs):

http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-07-015.html

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http://grants1.nih.gov/grants/guide/notice-

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Duplicate Applications/Activity Codes Change

- Identical applications may not be submitted; components of P series and certain K applications are exceptions

- Notice OD-09-100: http://grants1.nih.gov/grants/guide/notice-files/not-od-09-100.html

- An application can be submitted as new when a change in activity code (e.g., R01 to R21) occurs, as long as one of them is withdrawn

Center for Scientific Review (CSR)

National Institute of Allergy and Infectious Diseases

NIH Receipt/Referral/Review System for Research Grant Applications

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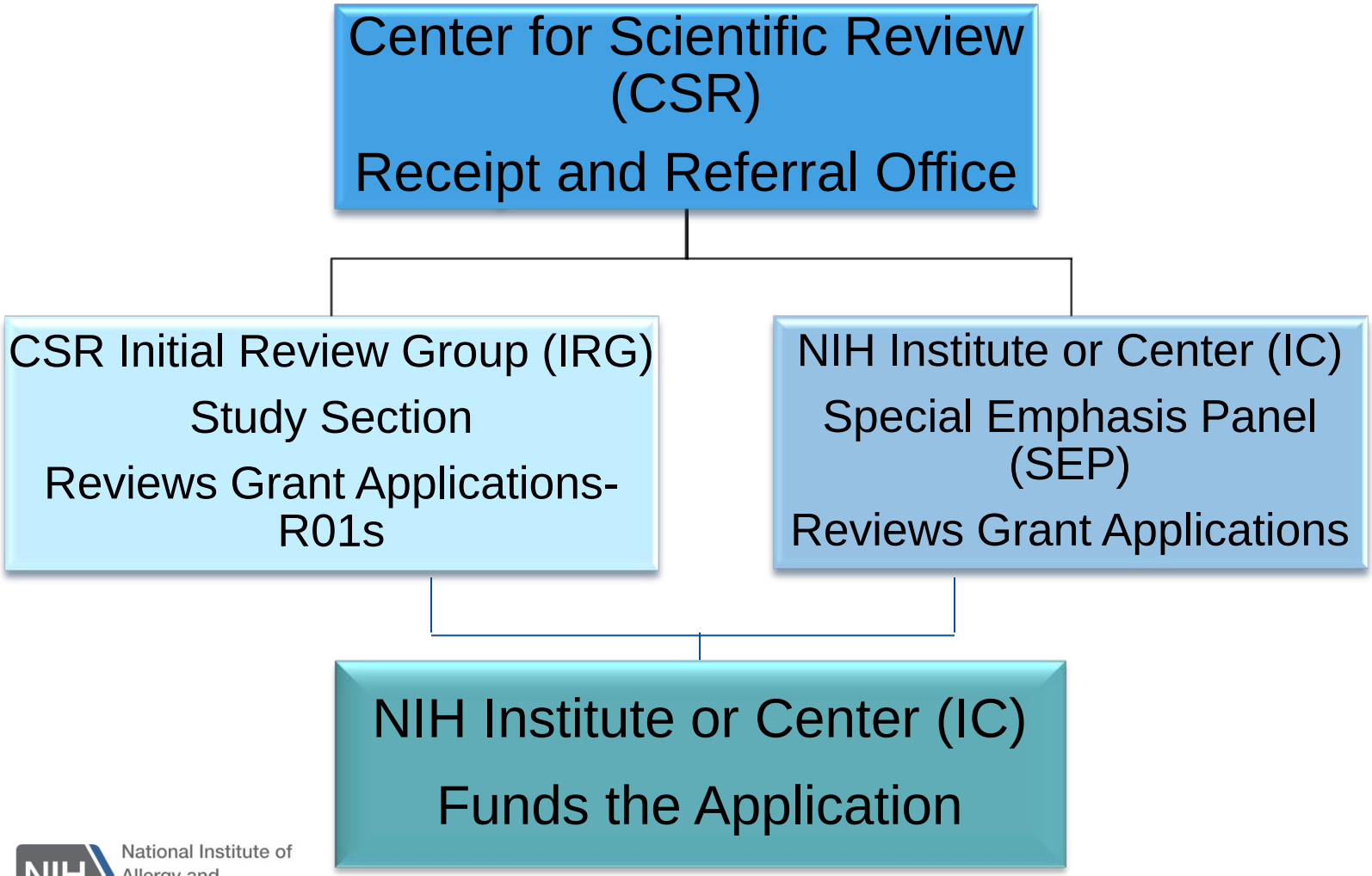
CSR Receipt of Applications

- CSR receives competing grant applications for the NIH

- CSR also receives and processes applications for:
  - Agency for Healthcare Research and Quality (AHRQ)
  - Centers for Disease Control (CDC)
    - National Institute of Occupational Safety and Health
    - Small Business Programs
  - Food and Drug Administration (FDA)
  - Agency for Children and Families (ACF)
  - Office of the Secretary, DHHS

Grant Application Assignment upon Receipt at NIH



NIH National Institute of Allergy and Infectious Diseases

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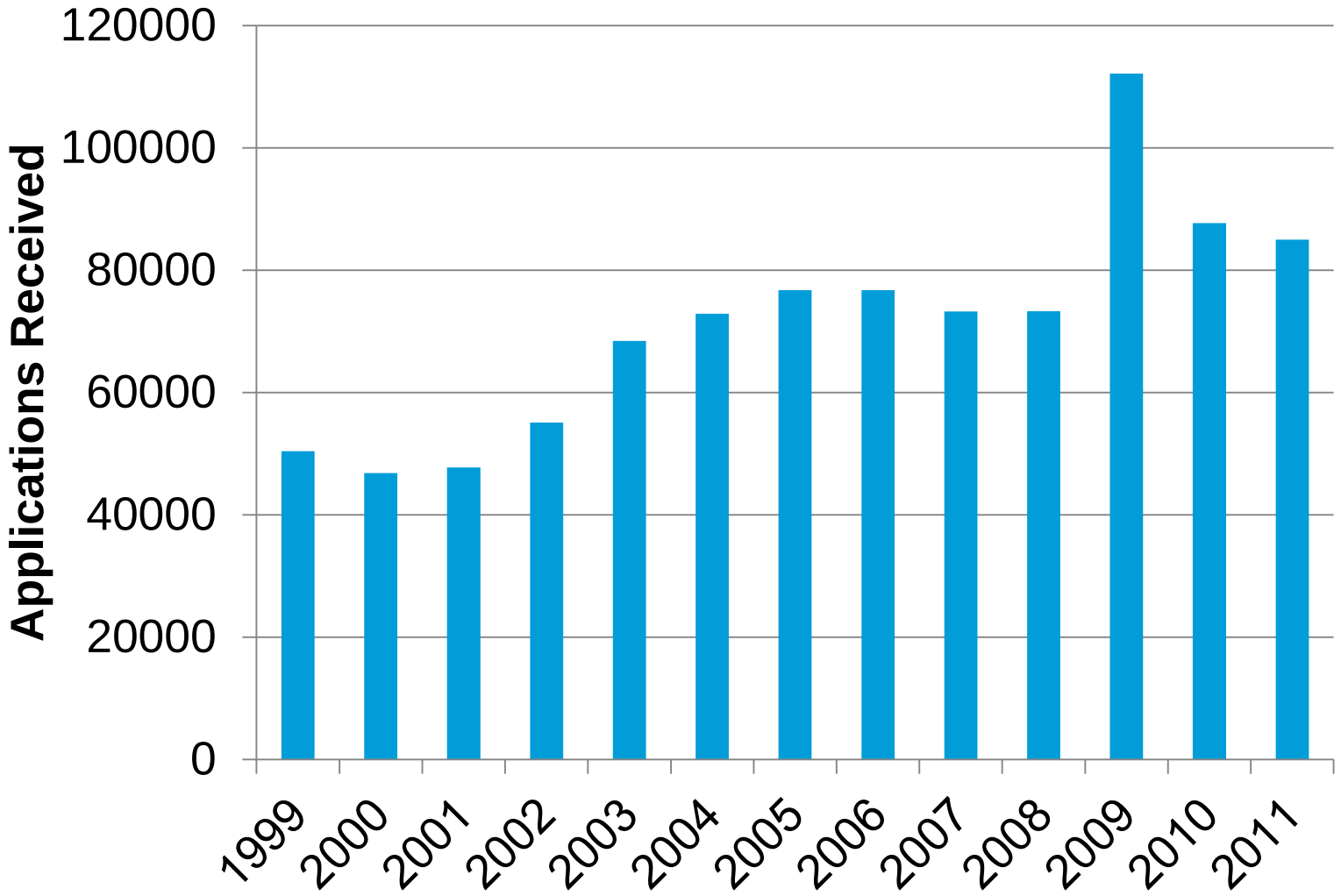
Applications Received at CSR by Fiscal Year



NIH National Institute of Allergy and Infectious Diseases

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Breakdown of Reviewed Applications

Fiscal Year	Total	Non-NIH*	IC	CSR
2011	80,519	3926	19,049	57,544
2010	85,182	3770	19,958	61,454
2009	98,220	3209	24,137	70,874
2008	69,139	1423	19,128	49,956
2007	73,435	1821	21,658	49,956
2006	74,111	1923	20,248	51,940
2005	73,611	1898	19,879	51,834
2004	69,835	2214	20,260	47,361
2003	60, 321	900	17,494	41,927
2002	49,667	1026	14, 560	34,081
2001	44,194	1004	12,501	30,689
2000	44,653	904	11,621	32,128

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Peer Review Goals

- Identify grant applications and contract proposals with the best science/highest scientific and technical merit for funding
- Objective, fair and equitable review of all submitted applications
- Unbiased review

First Level of Review: Scientific Review Group

- Initial peer review meetings are organized by either the Center for Scientific Review (CSR) or another NIH IC using Scientific Review Groups (SRGs)

- Research focus of the review is specified in the Funding Opportunity Announcement (FOA)

First Level of Review: Scientific Review Group (cont.)

- Peer review meetings are announced in the Federal Register: http://www.gpoaccess.gov/fr/index.html
- Notice includes the meeting title, date, place, roster of SRG panel members and involved NIH staff
- Meetings are closed to the public, although some meetings may have an open session

Peer Review: Roles

- Scientific Review Officer (SRO)
- Chairperson
- Reviewers
- Other NIH Staff
  - Program staff
  - Grants Management staff
  - Support Staff

Peer Review: SRO Roles

- The SRO is an extramural staff scientist and the Designated Federal Official for the review who
  - Coordinates peer review
  - Manages Conflict of Interest (COI)
  - Presides over a scientific review group and meeting

Peer Review: SRO Roles (cont.)

- Acts as an intermediary between applicants and reviewers
- Prepares summary statements for applications after review from meeting notes and reviewers' critiques
- Ensures protection of confidentiality for the review

Peer Review: SRO Roles (cont.)

- SRO checks applications for completeness, compliance and responsiveness to the FOA specific review criteria
- Identifies scientific expertise in the applications
- Develops the COI list from the applications
- Recruits reviewers and ensures that they complete the COI list

Peer Review: SRO Roles (cont.)

- Assigns reviewers to evaluate specific applications based on their expertise and mindful of their conflicts
- Selects the Chairperson, key dates for the review and meeting venue, if applicable
- Ensures that conflicted reviewers leave the room during the meeting

Conflict of Interest

- A COI exists when a reviewer has an interest in an application that is likely to bias his or her evaluation of it.
- A reviewer who has a real or apparent COI with an application, as defined in 42 CFR Part 52h (http://grants.nih.gov/grants/policy/fed_reg_peer_rev_20040115.pdf), may not participate in its review unless a waiver is granted by the NIH Deputy Director for Extramural Research.

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-120.html

Types of Conflicts of Interest

- Individuals participating with major professional roles (e.g., PD/PIs, key personnel, significant contributors and collaborators)
- Professional relationships (publications, mentors, reference letters, general letter of support)
- Applicants to an Request for Applications (RFA), FOA
- SRG membership

Peer Review Roles: Chairperson

- Serves as moderator of the discussion of scientific and technical merit of the applications under review
- Ensures that applications are reviewed objectively and fairly
- Has assigned reduced number of grant applications as a peer reviewer for the meeting

Review Panel Assembly

- Review panel consists of qualified reviewers based on scientific and technical qualifications and other considerations
  - Peer respect and expertise in their scientific field
  - Dedication to high quality, fair, and objective reviews
  - Ability to work collegially in a group setting

Review Panel Assembly (cont.)

- Ability to work collegially in a group setting
- Experience in research grant review process and NIH funding
- Balanced gender, minority representation
- Geographic distribution of reviewers

Reviewer Responsibilities

- Disclose their conflicts of interest from the COI list provided by SRO
- Certify to maintain confidentiality regarding all review proceedings and review materials
- Read assigned applications and prepare a written critique that addresses the review criteria

Reviewer Responsibilities (cont.)

- Assign numerical scores for each review criterion

- Make recommendations concerning
  - Scientific and technical merit of applications under review
  - Additional review criteria, including protection of human subjects
  - Budget requests and project duration

Peer Review Criteria and Considerations

- Scored Review Criteria

1. Significance
2. Investigator(s)
3. Innovation
4. Approach
5. Environment

Peer Review Criteria and Considerations (cont.)

Additional Review Criteria
Not scored individually, but considered in overall score

- Protection of Human Subjects
- Inclusion of Women, Minorities and Children
- Vertebrate Animals
- Biohazards

Peer Review Criteria and Considerations (cont.)

Additional Review Considerations
Not scored individually and not considered in overall score

- Justifications of involvement of Non-U.S. Organizations
- Select Agents
- Resource Sharing Plans
- Budget & Period of Support

Peer Review Scoring Chart

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
Moderate	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

Minor: An easily addressable weakness that does not substantially lessen the impact of the project
Moderate: A weakness that lessens the impact of the project
Major: A weakness that severely limits the impact of the project

Non-numeric score options: NR = Not Recommended for Further Consideration

DF = Deferred, AB – Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

Peer Review Process

- Reviewers receive access to applications and other review-related information from SRO 4-6 weeks prior to review
  - Internet Assisted Review (eRA commons)
    - Submit critiques
    - Post preliminary criterion scores and Overall Impact score
  - Overall Impact: for scientific/technical merit reflects: "*assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five 'criterion scores"*

Peer Review Meeting

- Decision of non-competitive applications by reviewers
  - Application does not necessarily lack scientific merit
  - Non-competitive in the pool of applications received
  - Preliminary scores are used to determine which applications will be discussed in full and non-competitive applications are not discussed (ND)

Peer Review Meeting (cont.)

- Assigned reviewers summarize major strengths and weaknesses for each review criterion
- An open floor discussion follows
- Discussion of other review criteria *(*e.g., HS, G, M, C, VA, etc.) follows
- Reviewers assign an overall impact/priority score utilizing a 9-point rating scale (1=exceptional; 9=poor)
- All eligible (unconflicted) members record an overall impact/priority score

Peer Review Meeting (cont.)

- Each member's score reflects his/her evaluation of the overall impact that the project is likely to have on the research field(s) involved, rather than a calculation of the reviewer's scores for each criterion
- Other review considerations are discussed
  - Justifications of non-US organization involvement
  - Select Agent
  - Resource Sharing Plans
  - Budget and Period Support

Peer Review Meeting (cont.)

- Each application stands on its own merit; applications are not compared with each other
- Reviewers evaluate the application as provided by the PI following the set review criteria
- The SRO takes notes and later writes the Resume and Discussion section of the Summary Statement

Post-review Meeting

- Priority scores are recorded and checked
  - Scores are averaged and rounded to obtain the overall impact score

    Example: Final overall impact score calculation

    (1+1+1+2+2+2+3+3+3)/9 * 10 = 20
- Final overall impact scores range from 10 (high impact) through 90 (low impact)
- Final overall impact score is reported on the summary statement
- Numerical impact scores are not reported for applications that are not discussed (ND)

Post-review Meeting (cont.)

- PIs can access their final averaged Overall Impact Score and Summary Statement at the eRA Commons site 4-6 weeks post-review
- Summary Statements include critiques from assigned reviewers as well as meeting notes
- ND applications also receive Summary Statements

- PIs can revise and resubmit one time if not awarded

Post-review Meeting- Summary Statements

- Summary Statements are prepared
  - Priority Score and Percentile Ranking for R01s
  - Overall Resume and Summary of Review Discussion section written by the SRO
  - Essentially unedited reviewers critiques are included
  - Budget recommendations are added
  - Administrative notes included

Summary Statements: Cover Page

SUMMARY STATEMENT
(Privileged Communication)

PROGRAM CONTACT: [redacted]

Release Date: [redacted]

Application Number: 1 R01 AI090[redacted]

Principal Investigator
[redacted]

Applicant Organization: [redacted]

Review Group: [redacted]
National Institute of Allergy and Infectious Diseases Special Emphasis Panel
[redacted]

Meeting Date: [redacted]
RFA/PA: [redacted]
Council: MAY 2010
PCC: A26G
Requested Start: 07/01/2010

Project Title: [redacted]

SRG Action: Impact/Priority Score: 63
Human Subjects: 44-Human subjects involved - SRG concerns
Animal Subjects: 44-Vertebrate animals involved - SRG concerns
Gender: 4U-Gender representation unknown, scientifically unacceptable
Minority: 4U-Minority representation unknown, scientifically unacceptable
Children: 4U-Child representation unknown scientifically unacceptable

Summary Statements: Page 1

1 R01 AI090 [redacted] 2 [redacted]

1R01AI090 [redacted]

BIOHAZARD COMMENT
CHIMPANZEES
INCLUSION OF CHILDREN PLAN UNACCEPTABLE
INCLUSION OF MINORITIES PLAN UNACCEPTABLE
INCLUSION OF WOMEN PLAN UNACCEPTABLE
PROTECTION OF HUMAN SUBJECTS UNACCEPTABLE
SCIENTIFIC REVIEW OFFICER'S NOTES
VERTEBRATE ANIMALS UNACCEPTABLE

RESUME AND SUMMARY OF DISCUSSION: [redacted] Based upon the evaluation of scientific and technical merit, this application received an Overall Impact/Priority score of 63.

DESCRIPTION (provided by applicant): [redacted]

Summary Statements: Critique Pages

CRITIQUE: The comments in the CRITIQUE section were prepared by the reviewers assigned to this application and are provided without significant modification or editing by staff. They are included to indicate the range of comments made during the discussion, and may not reflect the final outcome. The RESUME AND SUMMARY OF DISCUSSION section summarizes the final opinion of the committee after the discussion and is the basis for the assigned Impact/Priority score.

CRITIQUE 1:
Criterion Scores Table

Significance:	5
Investigator(s):	3
Innovation:	7
Approach:	7
Environment:	2

Overall Impact:
Strengths

- [redacted]

Weaknesses

- [redacted]

1. Significance:
Strengths

- [redacted]

Weaknesses

- [redacted]

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Summary Statements: Back Pages

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): Code 44. UNACCEPTABLE RISKS AND/OR INADEQUATE PROTECTIONS

- The applicants state that they will be using PBMC obtained from blood samples provided from [redacted] It is not clear whether this involves human subjects research, because there is no information provided in the application about whether or not the applicants will have access to donor records, or will be interacting with a living person to obtain new blood samples.
- There is also no information on the population from which the human blood samples will be obtained.

INCLUSION OF WOMEN PLAN (Resume): UNACCEPTABLE. G4U

- There is no information in the application about the population from which the human blood samples are obtained.

INCLUSION OF MINORITIES PLAN (Resume): UNACCEPTABLE. M4U.

- There is no information in the application about the population from which the human blood samples are obtained.

INCLUSION OF CHILDREN PLAN (Resume): UNACCEPTABLE. C4U

- There is no information in the application about the population from which the human blood samples are obtained.

Summary Statements: Back Pages (cont.)

VERTEBRATE ANIMALS (Resume): UNACCEPTABLE. Code 44

- The applicants will be using blood samples from chimpanzees and Sooty Mangabeys [redacted]
- The NIH requires that the applicants address all five points related to the use of live vertebrate animals. 1) There is no information on the animals themselves, including gender, age, weight, strain; 2) or justification/rationale for numbers of animals to be used. 3) The use of samples from these animals is also unclear, including volume of blood to be taken and/or pooled, or individual sample sizes/group; 4) veterinary care is not listed, nor are procedures for minimizing discomfort, distress, pain or injury including analgesic/ anesthetic drugs; and, 5) acceptable methods of euthanasia are not provided in the application. Each of these five points must be addressed in the Vertebrate Animals Section of NIH grant applications in which animals are used.

BIOHAZARD COMMENT: UNACCEPTABLE

- Some samples will be infected with laboratory strains of virus, but there is no mention in the application of how these samples will be managed for biohazard risk.

Second Level of Review: Advisory Council

- Advisory Council/Board of the potential awarding IC performs the second level of review

  - Composed of scientists from the extramural research community and public representatives (NIH Federal Advisory Committee Information: http://ofacp.od.nih.gov/)

Second Level of Review: Advisory Council (cont.)

- Members are chosen by the respective IC and are approved by the Department of Health and Human Services

- For certain committees, members are appointed by the President of the United States

Recommendation Process

- NIH program staff members examine applications, their overall impact scores, percentile rankings and their summary statements and consider these against the IC's programmatic needs
- Program staff provide a grant-funding plan to the Advisory Board/Council
- Advisory Board/Council also considers the IC’s goals and needs and advises the IC director
- IC director makes final funding decisions based on staff and Advisory Council/Board advice

Key NIH Staff Responsible for Funding Decisions

The Institute Director

- Factors Considered
  - Scientific merit
  - Contribution to IC mission
  - Program balance
  - Availability of funds

- Awards are made to applicant institutions

The Seven Habits of Highly Successful Applicants

1. **Collaborative** - work with other experts
2. **Bold** - propose solid, significant, scientific ideas
3. **Skillful** - present science in a clear, compelling, complete and easy-to-review manner
4. **Conscientious** - follow all instructions carefully
5. **Vigilant** - be aware of changes in policy and science
6. **Careful** - respond to critiques
7. **Diligent** - never give up!

NIH Grant System/Peer Review

Thank you!

Questions?