

The NIH Review Process

NIH Post Doctoral Fellows

June 29, 2010

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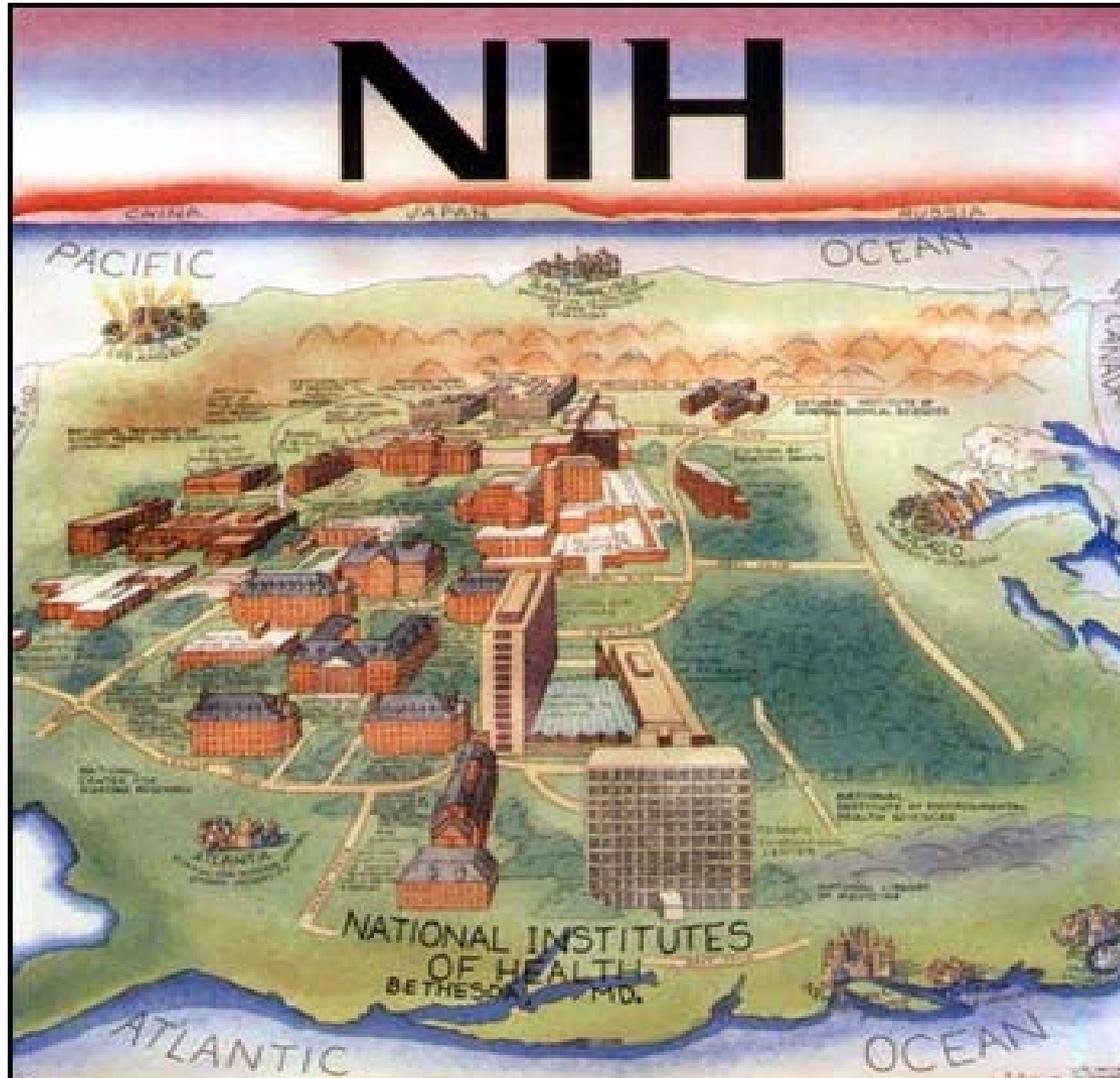
Division of Scientific Review

National Institute of Child Health & Human Development

National Institutes of Health



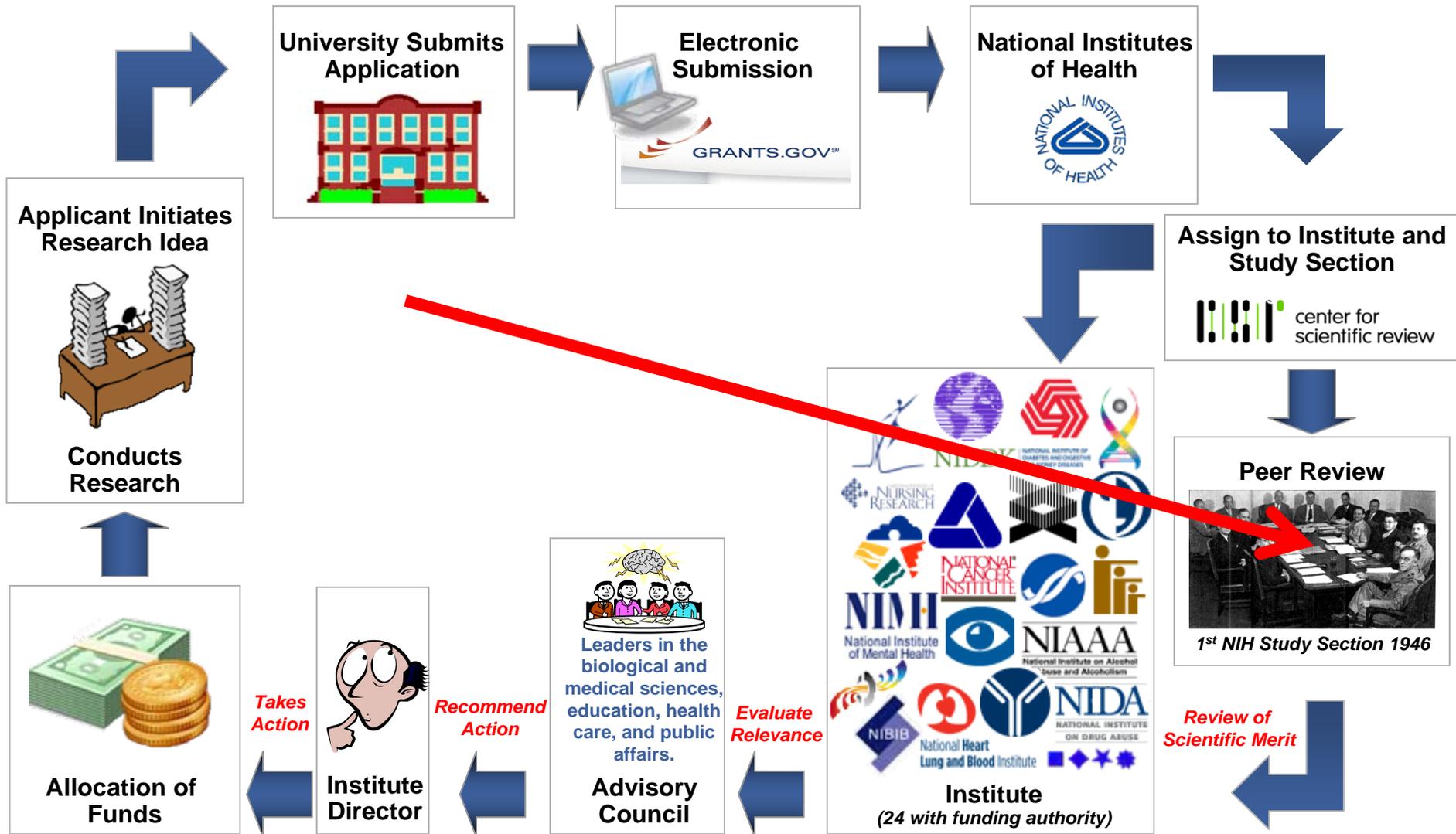
Our Focus



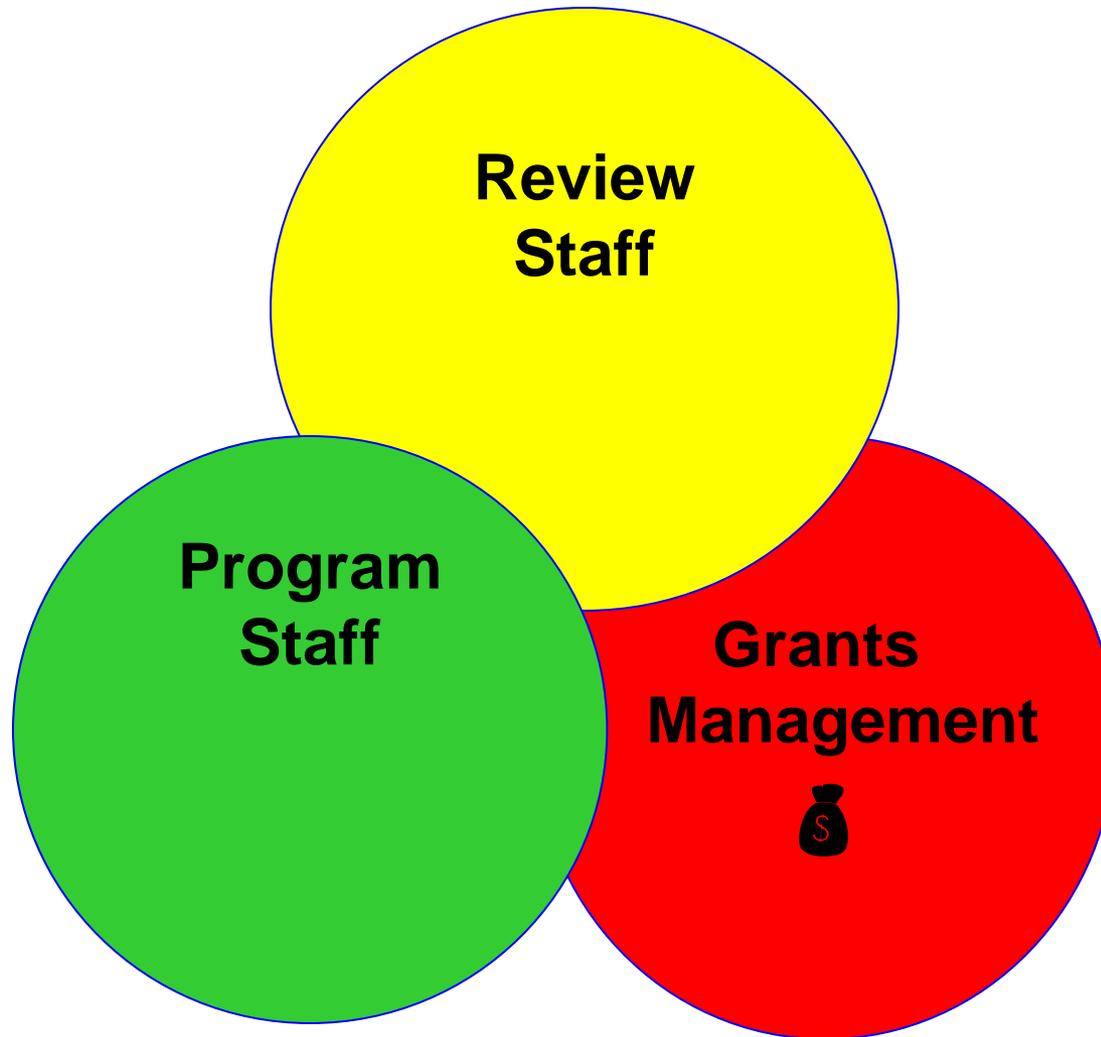
Goals

- (1) Encourage NIH-funded research
- (2) Dispel myths about NIH Review that can discourage and divert attention
 - a “closed” meeting

The NIH Funding Cycle



NIH Extramural Team



NIH Contacts: A Matter of Timing

Before Applying:

Program Officers [POs]

After Submitting:

**Scientific Review
Officers [SROs]**

After the Review Meeting:

(for top scoring applicants)

**Program Officers
Grants Officers**

Unusual Aspects of NIH Review

1: Independent authority of
Scientific Review Officers
and Program Officers

Scientific Review

round 'n round – up 'n down



***** PREMEETING PHASE *****

Step One: Placement of the application for review
at Center for Scientific Review or
an NIH Institute or Center

Where Applications are Reviewed: CSR or Institute/Center

Center for Scientific Review

- Research Projects (R01; R03; R21)
- Academic Research Enhancement Awards (R15)
- Postdoctoral Fellowships (F32)
- Small Business Innovation Research- SBIR (R43; R44)
- Shared Instrumentation
- ...

NICHHD (an example)

- Research Projects (R03)
- Program Projects – P01
- Centers (P30; P50)
- Conference Grants (R13)
- Career Awards (Ks)
- Cooperative Agreements (Us)
- RFAs
- ...

Implications for Applicants

- Study the range of expertise in the study group likely to review your application
- Include a cover letter to influence process
- Clear & informative title
- Clear & informative abstract

Types of Study Groups at NIH (both at CSR and ICs)

- **Standing Committees**

- Chartered; multi-year commitment
- Temporary members added as needed

CSR: <http://www.csr.nih.gov/Committees/rosterindex.asp>

NICHD: http://www.nichd.nih.gov/funding/dsr_sub.htm

- **Special Emphasis Panels (SEPs)**

- All Temporary (Ad-hoc) members

<http://era.nih.gov/roster/#sep>

***** PREMEETING PHASE *****

Step Two: Placement in specific study group &
Scientific Review Administrator

Assignment to a Study Section

Sources of influence:

- Applicant's cover letter
- Previous review history of application
- Mechanism of Application (CSR vs. IC)
- Research area

Reviewer Recruitment Process

1. Administrative review of applications

- analyze applications; determine expertise needed
- decide if it fits well enough or needs separate review (SEP)

Program

- **Necessary:** eligibility/responsiveness of application
- **Nice:** identify expertise needed

2. Sources of reviewers

- Previous reviewers (for continuity if resubmitted or renewal)
- SROs knowledge of field/scientists
- PO suggestions
- References in application
- NIH-funded researchers
- Professional resources (directories/conf programs)

Selection of Reviewers

- Expertise: publications & position
- Availability vis-à-vis NIH (on study section)
- COI (more later)
- Composition of panel (expertise/current affiliations)
- NIH funding & history as reviewer
- Previous work at NIH (known to be reliable, timely, sufficient detail, respectful to other reviewers)

Confidentiality

- “Closed” entire process and meeting
 - for all present: reviewers, program, grants, visitors [co-funders]
- At start of the meeting, SRO reminds everyone of the need for confidentiality – for all materials associated with the review (special email to Phone Reviewers)
- Public Info: Name of meeting, Date, Location, Roster
- **No statute of limitations**

Conflict of Interest/1

Bases for conflicts of interest:

- employment;
- financial benefit;
- personal relationships;
- professional associates;
- standing review group membership;
- multi-site or multi-component projects; &
- longstanding disagreements.

Conflict of Interest/2

- Most COI concerns inappropriate advantage for the application
- COI also includes inappropriate disadvantage for the application

Internet Assisted Review

- **SUBMIT PHASE:** Reviewers submit premeeting critiques and preliminary scores.
- **READ PHASE:** Reviewers read each others' critiques.
- **EDIT PHASE:** Reviewers submit post-meeting edited version of critique.

Review Criteria

- ❖ Listed in each Funding Opportunity Announcement
- ❖ The only topic of conversation during review

Review Criteria for R01s & R03s

1. Significance
2. Investigators
3. Innovation
4. Approach
5. Environment
 - Humans/Inclusions Protections
 - Animal Welfare

SCORING

Budget

Review Criteria for R01s & R03s/1

- 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?
- 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?

Review Criteria for R01s & R03s/2

- 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?

Scores

Individual Reviewers' Scores	1 → 9
Application's Impact Score	10 → 90

Scoring

Criterion Scores

R01s and R03s	Ks
1. Significance	1. Candidate
2. Investigators	2. Career Development Plan
3. Innovation	3. Research Plan
4. Approach	4. Statements by Mentor, Co-Mentor(s), Consultant(s), and Collaborator(s)
5. Environment	5. Environment and Institutional Commitment to the Candidate

Overall Impact Score

Unusual Aspects of NIH Review

2: Reviewers decide on the weighting of various criteria when deciding on the Overall Impact Score

Impact/Priority/Final Scores

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

The NIH Grant Application Scoring System

	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High Impact	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	<i>Excellent</i>	<i>Very strong with only some minor weaknesses</i>
Moderate Impact	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 Impact	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

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

Minor Weakness: An easily addressable weakness that does not substantially lessen impact

Moderate Weakness: A weakness that lessens impact

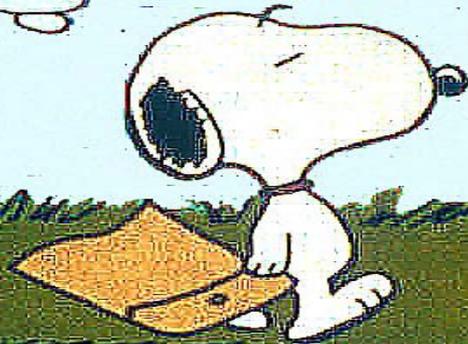
Major Weakness: A weakness that severely limits impact

Not Discussed (ND) Applications

About half of the applications are ND

- **Purpose:** so that the review meeting can focus discussions on the most competitive applications
- **No *Overall Impact Score* or *Resume of Discussion***
- **Receive: *Summary Statement* with *Criterion Scores & Critiques* from assigned reviewers**

HERE'S THE WORLD FAMOUS
SCIENTIST MAILING IN HIS
LATEST APPLICATION...



I HAVE A HARD TIME
BELIEVING THEY READ
IT VERY CAREFULLY...



*** MEETING PHASE ***

- In-person or phone review or computer-based
(also, phone reviewers for in-person reviews)
- Sharing of information starts with Internet Assisted Review

What Happens at the Meeting/1

- Scientific Review Officer as Designated Federal Official (DFO): Introduction with required reminders about confidentiality; COI; scientific misconduct; scoring
- Reviewers esign COI forms before and after meeting
- Applications in bottom half considered as Not Discussed

What Happens at the Meeting/2

For each remaining application

- COIs leave the room
- Assigned Reviewers for that application
 - initial “temperatures”/scores (possible to be ND)
 - Primary Reviewer initiates with brief overview, then 2nd, 3rd, reader
- General Discussion
- Protections (humans/animal) & Inclusions
- Assigned Reviewers: final scores/range defined
- **Scoring** (private)
- Budget



*** POST MEETING PHASE ***

- Scores/ND entered within 48 hours
- Applicants can access via their Commons accounts
- SRO prepares Summary Statement for each application, writing Resume of Discussion for scored applications;
- SRO releases Summary Statements; applicants, POs can access via their Commons accounts

Summary Statement for Scored (Discussed) Applications

- **Impact Score**
- Resume and Summary of Discussion
(written by SRO)
- Criterion Scores and Critiques from assigned reviewers
- Human Subjects (Codes for Inclusion of Women/Minorities/Children - Vertebrate Animal
- Budget Recommendations
- Administrative Notes (eg., overlap)

For Each Reviewed Application

➤ Summary Statement

&

➤ *Impact Score*: Scientific Merit Rating,
from 10 (best) to 90 (weakest) or

➤ *Not Discussed* or

➤ Deferred or

➤ *Not Recommended for Further Consideration*

Decision-Making Process

1. Peer Review: **scientific & technical merit**

- *Program Staff Recommendation: program priorities*

2. Institute National Advisory Council

- *Director's Decision: programmatic priorities and availability of funds*

Applications from Foreign Organizations/1

- Request budgets in U.S. dollars;
- Prepare detailed budgets for all applications;
- Not include any charge-back of customs and import fees;
- Comply with the format specifications, which are based upon a standard U.S. paper size of 8.5" x 11" within each PDF;
- If appropriate, request funds for up to 8% Facilities and Administrative (F&A) costs (excluding equipment);
- Comply with Federal/NIH policies on human subjects, animals, and biohazards; and
- Comply with Federal/NIH biosafety and biosecurity regulations.
- Proposed research should provide special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States (U.S.) or that augment existing U.S. resources;
- Indicate how the proposed project has specific relevance to the mission and objectives of the NIH/IC and has the potential for significantly advancing the health sciences in the United States

Applications from Foreign Organizations/2

The applicants need to justify what is unique about their application in the budget justification section.

● * * * *

REVIEW:

Applications from Foreign Organizations. As applicable for the FOA or submitted application, 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.

Minority Inclusions: “only foreign” (M5)

Resubmissions

- Be in a constructive frame of mind
- Show appreciation for reviewers' brilliant insights into the important contributions your research is likely to produce and the guidance they have offered
- Evaluate the summary statement for strengths and weaknesses
- Determine whether fatal weaknesses have been identified
- If “go ahead” -
list each major concern and respond to each
- State how responses will be identified

General Strategies to Strengthen Applications: The Short List

- Ask scientist with NIH support to critically review your application prior to submission – more than once
- Talk with an NIH program officer

Art of Persuasion: Assumptions

- that the reviewers are generally knowledgeable and committed to doing a thorough job of evaluating each application
- that the reviewers have less time to complete the task than desirable
- that good formatting will assist reviewers to remember your organization and the thrust of your arguments

Help Reviewers See the Merits

- Think like a reviewer
- Learn as much as possible about the NIH Review System (e.g., figure out the likely study section - don't include a member of that study section on your application)
- Include collaborators who can compensate for your deficiencies

Success

- Diversify – your scientific studies, your potential funding sources
- Know your funding agencies well
- Ask for help – from NIH & others - and help others
- Enjoy!