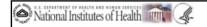


#### Peer Review of NIH Research Grant Applications

Anthony M. Coelho, Jr., Ph.D.

Review Policy Officer
Office of the Director NIH
Office of Extramural Research



#### Anthony M. Coelho, Jr., Ph.D.

#### **Experience:**

•Review Policy Officer 5 years

Chief - Clinical Studies and Training
 Section NIHBI and

**Scientific Review Administrator** 

•Peer Reviewer 12 years

•Funded Investigator 18 years

(NIH, DOE, EPA and Private Sector Funding)



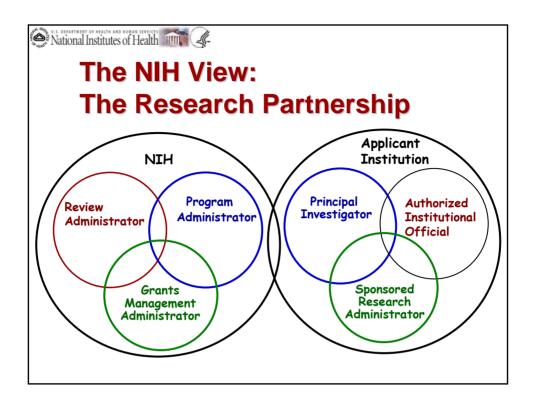
#### **Important Things to Know:**

- 1. The handout material is a reference resource
- 2. The handout contains more information than I will discuss
- 3. Information that is important is repeated to remind you that it is important

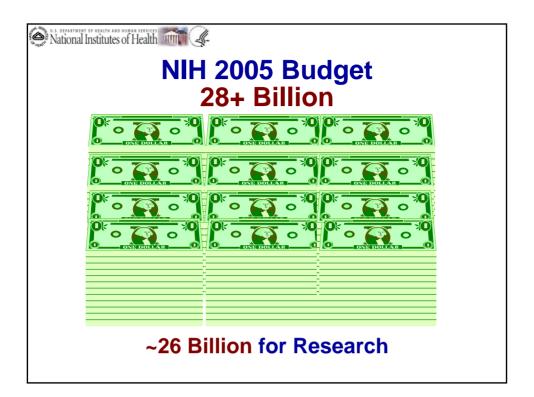


#### **Important Things to Know:**

- NIH Peer Review Process based on Laws
- NIH Peer Review Practices
   based on Culture and Behavior
   of Study Section Culture
- My objective is to help you understand both





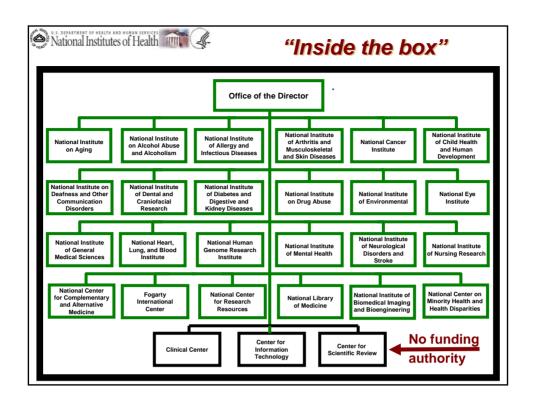


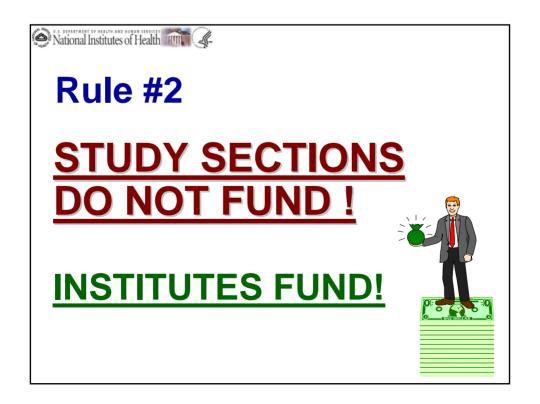




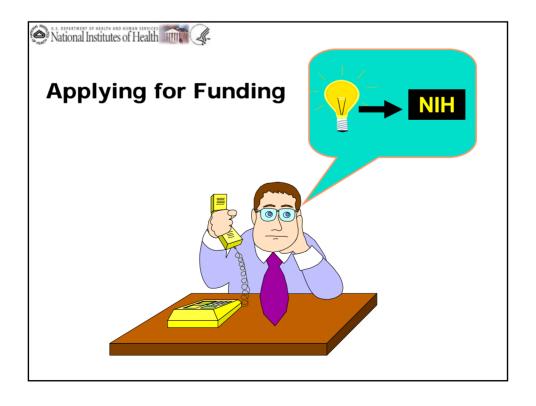
DO NOT write the application for Yourself unless you are going to fund it yourself

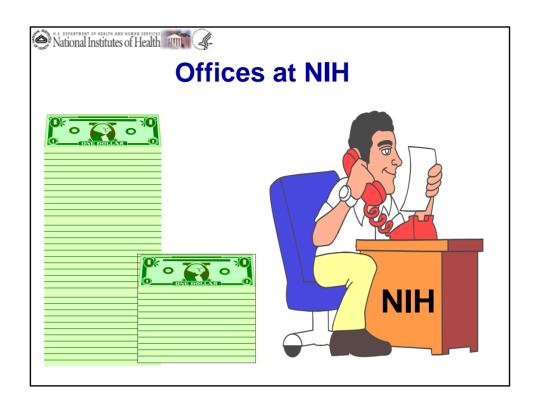
You MUST convince the entire review committee and the funding agency

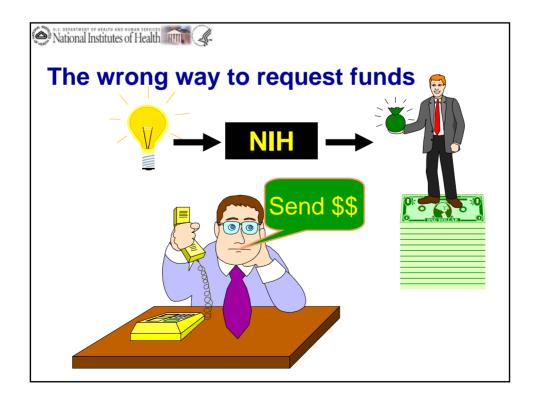


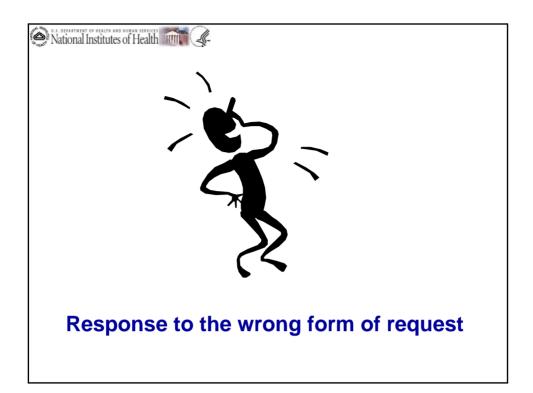


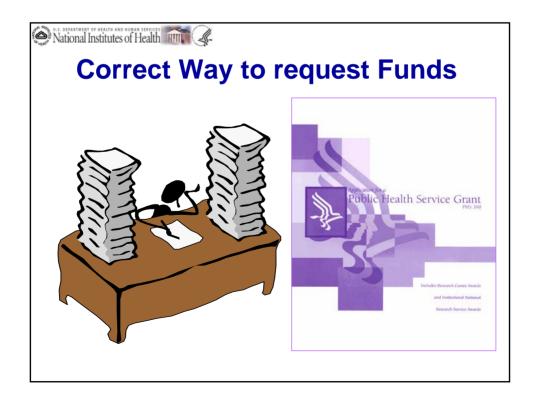
# Rule #3 You must satisfy the needs of reviewers and the needs of the funding agency

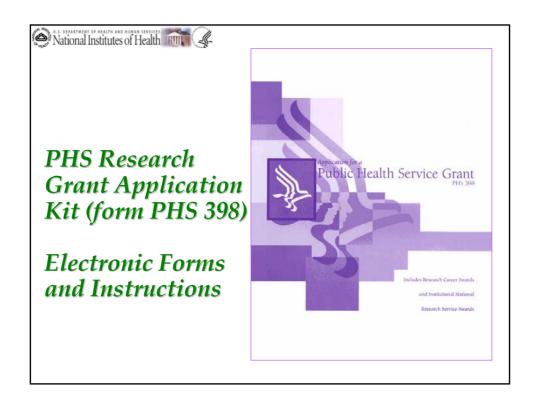


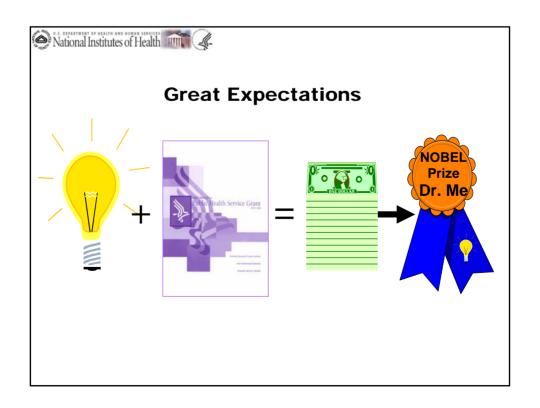


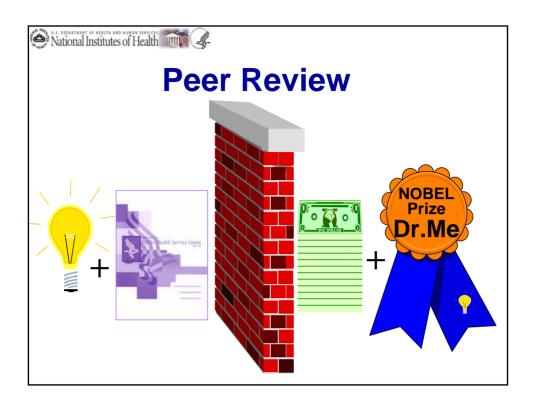


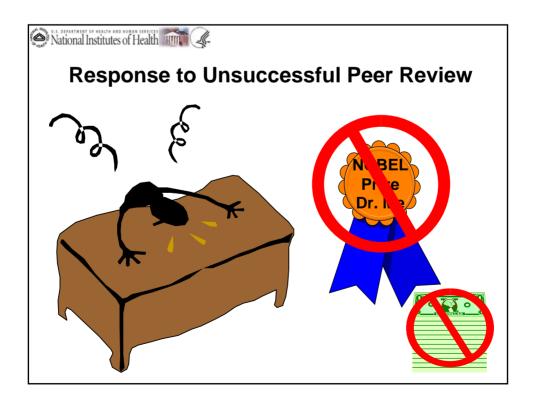




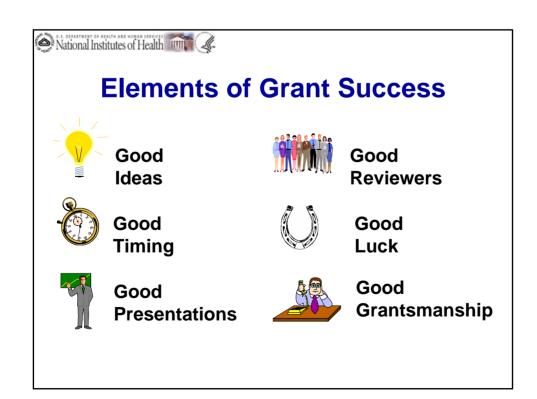














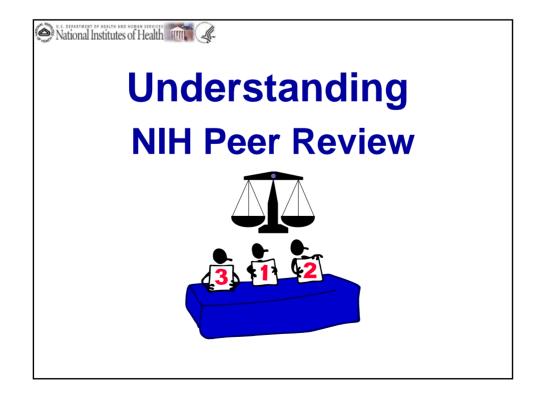
- •How to do it
- •When to do it
- •What to do when things don't go as planned
- \*Being willing to do what is needed
  - Passion and Commitment
- \*Doing it- doing what is needed
  - Commitment
  - \* Understanding Peer Review

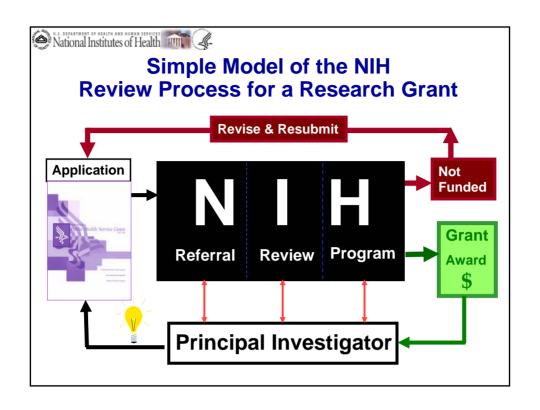


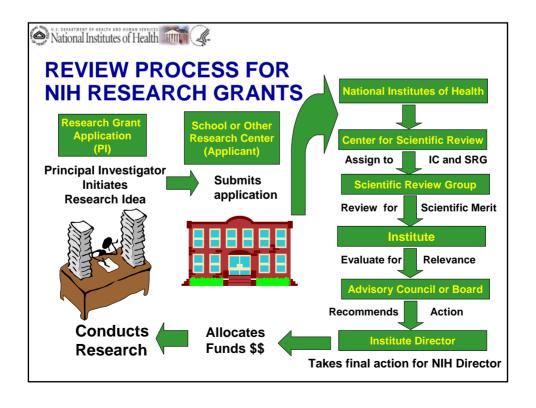
The "other" method of applying for grant funds













#### **Dual Review System for Grant Applications**

First Level of Review

#### Scientific Review Group (SRG)

Provides Initial Scientific Merit

**Review of Grant Applications** 

Rates Applications and

Recommends for Level of Support

and Duration of Award

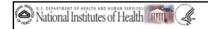


#### **Advisory Council**

Assesses Quality of SRG Review of Grant Applications

Makes Recommendation to Institute Staff on Funding

**Evaluates Program Priorities and Relevance Advises on Policy** 



#### STUDY SECTIONS JUDGE



#### **Scientific and Technical Merit**

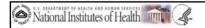
Institute staff use the evaluations as part of the process of considering the relevance of applications to the Institute's mission, research priorities and portfolio of existing research

#### STUDY SECTIONS DO NOT FUND!

#### **INSTITUTES FUND!**



# Grant Application Receipt and Assignment



#### **Applications Submitted to NIH**

- Approximately 65,000+ grant applications are submitted to NIH each year,
- 25-30% are funded
- Competing grant applications are received for three review cycles per year

National Institutes of Health				
Timeline				
Submission	Review	Post-Revie	w Phase	
Oct 1/Nov 1*'03	Feb Mar '04	Mar- Jun'04	May/Jun '04	Jul 1 '04
Feb 1/Mar 1* '04	Jun Jul '04	Sep 30'04	Sep/Oct '04	Dec 1 '04
Jun 1/Jul 1* '04	Oct Nov '04	Nov- Feb'05	Jan/Feb '05	Apr 1 '05
Standard Receipt Date (new/ *revised and continuation)	Initial Peer Review	Fur for	uncil Meeting; iding Approved Nonexpedited Special Action Awards	Awaru
Funds Released for Payline Grants Chosen for Expedited Second- Level Review				



#### Receipt Dates \* \*\*

#### **Depend on the Type of Application**

- Jan, May, Sept 10: Institutional Training Grant
- Jan, May, Sept 25: Academic Research Enhancement Award
- Mar, Jul, Nov 1: Revised, Competing Continuations, and Supplements
- April, Aug, Dec 1: Small Business Technology Transfer
- April, Aug, Dec 5: Individual NRSA
- April, Aug, Dec 1: Small Business Innovation Research
- May, Sept, Jan 1: AIDS

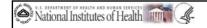
\*\* ALWAYS check with Institutes to verify dates

<sup>\*</sup> RFA and RFP dates defined in the solicitations



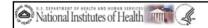
# ???? What Happens To Your Application When It Arrives at NIH ????





# Center for Scientific Review (CSR) Focal Point for Receipt and Referral

- Central receipt point for PHS applications
- •Referral to Institutes (Funding Components) and to Study Sections (Review Components)
- CSR study sections reviews of most investigator initiated research and research training applications for scientific merit



#### Assignment to CSR Study Sections

Applications assigned to study sections known as Scientific Review Groups (SRG) based on:

- 1. specific referral guidelines for each SRG and
- 2. information contained in your application

(Go to the Website <a href="http://era.nih.gov/roster/index.cfm">http://era.nih.gov/roster/index.cfm</a> to learn about study sections – their scientific mission and their scientific membership)

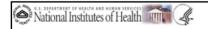


# WHO/WHAT DETERMINES WHICH GROUP REVIEWS THE APPLICATION?

Mechanism

Type of application CSR or Institute Review

- Referral and Review Staff
- Past Review History (if any) of application
- Principal Investigator
   Letter attached to application; self-referral



#### Peer Review of NIH Support Mechanisms

#### Who Reviews What ? CSR Institutes

Research Project Grant (R01)
Postdoctoral Fellowship (F32)
Senior Fellowship (F32)
Fogarty International Center
Fellowship (F05, F06)
Short-Term Training (T35)
Small Business Grants (R41, R42
R43, R44)
Academic Research Enhancement
Award (R15)
Biomedical Research Support
Shared Instrumentation
Grant (S10)

Program Project Grant (P01)
Center Grant (P30, P50, P60)
Institutional Fellowship (T32)
Academic Career Award (K07)
Mentored Clinical Scientist
Development Award (K08)
Conference Grant (R13)\*
Marc Fellowships (F34, F36, T34)
Minority Biomedical Support
Grant (S06)
Resource Grant (P40, P41, R24, R26, R28)
RFA - Request for Applications

R&D - Contracts

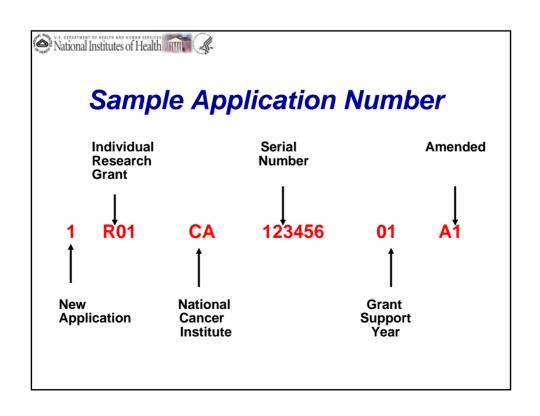


# WHO/WHAT DETERMINES WHICH GROUP REVIEWS THE APPLICATION?

#### YOU DO!

- The words that are in your application
- Your title
- Your abstract
- Your specific aims
- Your methods







#### Assignment Notification Letter

Dear Dr. Sample:

Your grant application entitled "CEREBRAL VESSEL INNERVATION IN HYPERTENSION" has been received by the National Institutes of Health and assigned to a Scientific Review Group (SRG) for scientific merit evaluation and to an Institute/Center for funding consideration. Specific information about your assignment is given below. The initial peer review should be completed by March, 2001, and a funding decision made shortly after the appropriate National Advisory Group meets in May, 2001. Questions about the assignment should be directed to the Scientific Review Administrator (SRA) or the Division of Receipt and Referral, Center for Scientific Review at (301) 435-0715. Other questions prior to review should be directed to the Scientific Review Administrator and questions after the review to the program staff in the Institute/Center.



#### Assignment Notification Letter (continued)

**Principal Investigator: Sample Pamela** 

Assignment Number: 2 R01 HL12345 - 12A1

**Dual Assignment: NS** 

#### **Scientific Review Group:**

Epidemiology and Disease Control Subcommittee 2 SS (EDC2)

A roster of the membership of this Scientific Review Group located on the following website:

http://era.nih.gov/roster/index.cfm



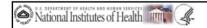
#### Assignment Notification Letter (continued)

#### **Scientific Review Administrator:**

DR. DAVID MONSEES, SRA CTR FOR SCIENTIFIC REV 6701 ROCKLEDGE DR RM 3199 MSC7802 BETHESDA MD 20892 (301) 435-0684

#### **Assigned Institute/Center:**

NATL HEART, LUNG, & BLOOD INST DIV/EXTRAMURAL AFFAIRS RK2 7100 NATIONAL INSTITUTES OF HEALTH BETHESDA, MD 20892 (301) 480-5295



#### Assignment Notification Letter (continued)

IMPORTANT NOTICE: Please review the information on human and animal subjects research located at:

http://grants.nih.gov/grants/peer/hum\_anim\_notice.pdf

as these requirements will affect the priority score on your application.



# Study Section Meeting: Scientific Review Groups



#### **TYPES OF REVIEW COMMITTEES:**

#### **Chartered Study Sections**

 when the subject matter of the application matches the referral guidelines for the standing study section

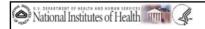
#### **Special Emphasis Panels (SEPs)**

- when the subject matter does not fit into any study section, or
- when assignment of an application to the most appropriate study section would create a conflict of interest, or
- Special Mechanisms (RFA, Fellowships, SBIRs, AREAS, etc.)



#### Study Sections at NIH

- Study Sections are managed by a Scientific Review Administrator (SRA) who is a professional (at Ph.D. or MD level) whose scientific background is close to the expertise of the study section
- Each standing study section has 12 24 members who are primarily from academia
- 60 100 applications are reviewed at each study section meeting
- Several hundred study section meetings
- Special Emphasis Panels vary in size and number of applications that they review per meeting



#### **SCIENTIFIC REVIEW GROUP**

#### **Scientific Review Administrator**

- •Recruits and selects reviewers
- •Insures that the review that is competent, thorough and fair (unbiased)
- •Proper review criteria used to evaluate application

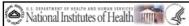
#### Reviewers

- Some charter members; some temporary members
- Scientists with appropriate expertise
- •High professional profiles
- •Dependable, reasonable, open minded



#### **Grants Technical Assistant**

- •Mails material to reviewers
- •Handles paperwork
- Organizes meeting room
- Enters scores and codes
- Assists with summary statements



#### Center for Scientific Review

Example of Varied Expertise on a Sample Study Section

<u>Surgery, Anesthesiology and Trauma Study Section</u> <u>Selected Areas of Competence of Members</u>

**Biochemistry** 

**Burn Physiology and Electrolyte Metabolism** 

**Cardiovascular and Pulmonary Physiology** 

**Clinical Anesthesiology** 

**Drug Metabolism (Anesthetics)** 

**General Surgery** 

Immunology and Transplantation

**Nutrition** 

Pharmacology (Analgesics, Narcotics and Antagonists)

**Pulmonary Embolism** 

Shock and Trauma

**Toxicology of Anesthetic Drugs** 

Vascular Surgery



### WHO ASSIGNS REVIEWERS TO MY APPLICATION?

Scientific Review Administrator

**Assignment to Specific Reviewers** 

- Based on application content
- Based upon expertise of reviewers
- · Based upon knowledge of the field
- May consult with Institute staff
- May consult with chairperson
- Suggestions from PI on type of expertise needed to evaluate (NEVER names)
- Considers review history



#### Criteria For Selection of Peer Reviewers

- Demonstrated Scientific Expertise
- Doctoral Degree or Equivalent
- Mature Judgment
- Work Effectively in a Group Context
- Breadth of Perspective
- Impartiality
- Interest in Serving
- Adequate Representation of Women and Minority Scientists



#### 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.





#### **Confidentiality**

- Review materials and proceedings of review meetings represent privileged information to be used only by consultants and NIH staff.
- At the conclusion of each meeting, consultants will be asked to destroy or return all review-related material.
- Consultants should not discuss review proceedings with anyone except the SRA.
- Questions concerning review proceedings should be referred to the SRA.



#### WHAT HAPPENS IN A STUDY SECTION MEETING?

- Closed to the public (FACA rules apply)
- Orientation

**Conflict of interest** 

Developments of interest to the study section

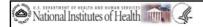
Changes in policy or procedure

Introduction of persons present Role of persons present

- Streamlining or list provisionally approved
- Application by application discussion
  - Persons with conflicts of interest excused
  - Assigned reviewers give preliminary scores
  - Discussion of application's scientific and technical merit
  - Assigned reviewers first, then other members
  - •Range of scores set

#### •Every member scores every application \*

 Assignment of gender, minority, and children codes, human subjects codes; recommended changes to budget



#### WHAT IS STREAMLINING?

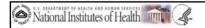
Process by which reviewers judge which applications are in the lower half of those assigned for review.

Applications in the lower half are evaluated by the reviewers prior to attending the meeting but they are not discussed at the Scientific Review Group meeting.

- Any member can object to the streamlining of an application
- Requires that all reviewers agree to streamline an application
- Streamlined applications receive written reviewer critiques

#### Why?

- · Shortens meetings
- Reviewers more willing to serve on committee
- Allows more time for discussion of applications



#### "Review" of Applications

- Applications are not reviewed at the meeting.
- They are evaluated prior to the meeting.
- The meeting is a time for discussion and negotiation of a priority score and for making a recommendation that best reflects the scientific and technical merit of the application.
- Strong applications get brief discussion
- Weak application get brief discussion
- Marginal application get longer discussion to ensure fairness to the applicant



#### **Review of Research Grants**

#### **REVIEW CRITERIA:**

- Significance
- Approach
- Innovation
- Investigator
- Environment

Described in detail in the PHS 398 application instructions



#### Review Criteria

- <u>Significance:</u> Does the study address an important problem? How will scientific knowledge be advanced?
- Approach: Are design and methods well-developed and appropriate? Are problem areas addressed?
- Innovation: Are there novel concepts or approaches? Are the aims original and innovative?
- <u>Investigator</u>: Is the investigator appropriately trained?
- Environment: Does the scientific environment contribute to the probability of success? Are there unique features of the scientific environment?



#### **Newly Revised Review Criteria**

- 1. Significance Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- 2. Approach Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- 3. Innovation Is the project original and innovative? Does the
  project challenge existing paradigms or clinical practice; address an
  innovative hypothesis or critical barrier to progress in the field?
  Does the project develop or employ novel concepts, approaches,
  methodologies, tools, or technologies for this area?
- 4. Investigators Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
- 5. Environment Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?



#### **Research Involving Human Subjects**

Important Considerations that must be addressed in the application because they impact on priority score - considered to be part of the Approach

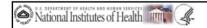
- Are there any risks\* to the human subjects?
- Are the protections adequate?
- Are there potential benefits to the subjects and to others?
- What is the importance of the knowledge to be gained?
- Are the plans for inclusion of minorities, both genders and children adequately addressed?
- Is the proposed study exempt from human subject review?
- No page limits
- \* "Risks" include the possibility of physical, psychological, or social injury resulting from research.



#### Research Involving Human Subjects

#### Areas of exemption

- Education Research
  - normal educational practices
- Educational Tests, Survey or Interview Procedures, or Observation of Public Behavior
  - subjects not identified
  - subjects' privacy rights protected
- Educational Tests, Survey or Interview Procedures, or Observation of Public Behavior Not Exempt in Previous Category if: subjects are public officials or public office candidates federal statute requires confidentiality without exception



#### **Research Involving Human Subjects**

#### Areas of exemption

- Collection or Study of Existing Data, Documents, Records, Pathological Specimens
  - information publicly available
  - subjects not identified
- Research and Demonstration Projects
   Regarding Certain Public Benefit or
   Service Programs
- Taste and Food Quality Evaluation and Consumer Acceptance Studies Using
  - foods without additives
  - U.S. Government approved food ingredient

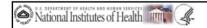


## Inclusion of Women and Minorities in Clinical Research

 Women and Minorities must be considered for inclusion in all clinical research supported by NIH

or

•Appropriate justification must be provided to explain why they are not included in the proposed research



#### Research Involving Children

Children must be considered for inclusion in all human subject research supported by NIH

or

Appropriate justification must be provided to explain why they are not included in the proposed research



#### Research Involving Children

Children must be considered for inclusion in all human subject research supported by NIH

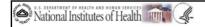
Effective for all new applications received after October 1, 1998

- Child is defined as an individual under age 21
- If children are included, Investigator must address
  - age range
  - expertise of investigative team
  - facilities
  - sufficient numbers



#### Research Involving Children

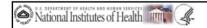
- If children are not included, must justify exclusion:
  - Topic irrelevant to children
  - Laws/regulations bar inclusion of children
  - Knowledge already available or being obtained
  - Separate study warranted
  - Unable to judge potential risk to children
  - Collecting data on pre-enrolled adults
  - Other special cases



#### Vertebrate Animals

#### **Important Considerations**

- Will the anticipated results be for the good of society?
- Will the work be planned and performed by qualified scientists?
- Will the animals be treated so as to avoid any unnecessary discomfort, pain, anxiety, or poor health?
- Species chosen?
- Animals in short supply?



#### Scientific Review Group or Study Section Actions

- Scored, Scientific Merit Rating
- Priority scores:
  - 1 (best) to 5 (poorest) and percentiles
- Unscored (lower half)
- Deferral

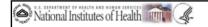


#### **Summary Statement**

After the review meeting is finished, the results are documented by the SRA in a summary statement and forwarded to the PI and to the assigned NIH Institute. The assigned NIH Institute is responsible for making a funding decision.

The summary statement contains:

- •Overall Resume and Summary of Review Discussion
- Essentially Unedited Critiques of Assigned Reviewer
- Priority Score and Percentile Ranking
- Budget Recommendations
- Administrative Notes



#### National Advisory Council or Board Review



#### **Council Actions**

- Assesses Quality of SRG Review
- Concurs with study section action or
- Modifies SRG (study section) action <u>Can not change priority score</u>
  - Deferral for re-review of the same application – no changes allowed
- Makes Recommendation to Institute Staff on Funding, Evaluates Program Priorities and Relevance and Advises on Policy



### NIH Policy does NOT allow Rebuttal of Peer Review outcome

There is an Appeal process however Differences of Scientific Opinion Can NOT be Appealed!

NIH policy permits appeal of review outcome if

- 1. Procedural error in review process
- 2. Factual errors (not differences of interpretations or understanding)



### REVISE & RESUBMIT

### **Do Not Appeal Review Outcome**

#### **NIH Appeal Outcomes:**

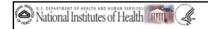
- 1. Council Denies Appeal (bad outcome)
- 2. Council Accepts Appeal: Original Application and Letter of Appeal is sent to the Same Study Section for a second examination and evaluation (bad outcome)
- 3. Council Accepts Appeal: Original Application be sent to a new Study Section but without the Letter of Appeal (bad outcome)

	Timeline Co		Revision		Appeal	
Submit	Feb (	-	Feb	-	Feb	
Review	June		June	-	June	
Council	Sept	04	Sept	04	Sept	04
Earliest award	Dec		'		'	
Review 2					Oct	04
Council 2					Jan	05
<b>Earliest Resubmission</b>			March	า05		
Earliest Award					AOK	05
Review 2			June	05		
<b>Earliest Resubmission</b>					July	05
Council 2			Sept	05		
Review 3					Oct	05
Earliest Award			Dec	05		
Council					Feb	06
Earliest Award					June	06



# What Determines Which Awards Are Made?

- Scientific merit +
- Program Considerations +
- Availability of funds



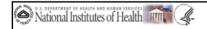
You do not want a reviewer to make this comment about your application:

"This application is characterized by ideas that are both original and scientifically important. Unfortunately the ideas that are scientifically important are not original and the ideas that are original are not scientifically important."



You do not want a reviewer to make this comment about your application:

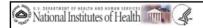
"In addition to proposing a research design that is a fishing expedition, the applicant also proposes to use every type of bait and piece of tackle ever known to mankind."



The research that you propose in your application must be innovative and focused



#### **NIH Information Sources**



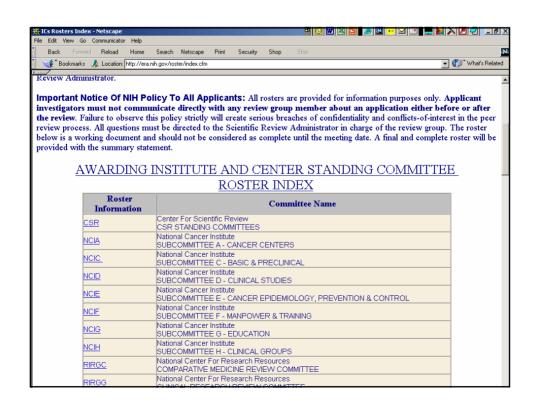
#### **NIH GUIDE**

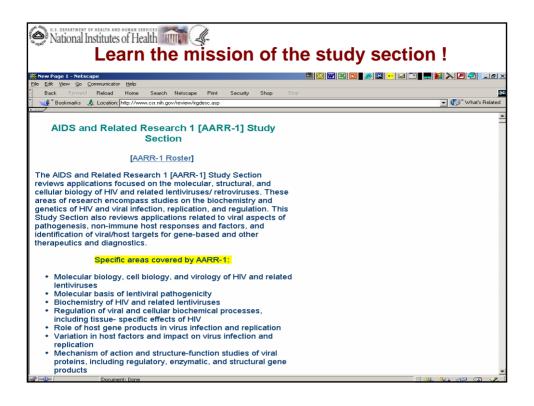
for Grants and Contracts

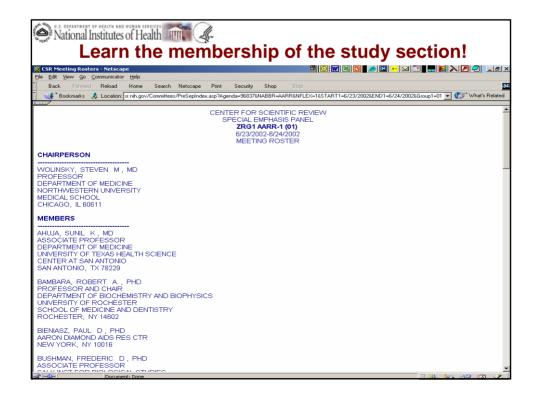
U.S. Department of Health and Human Services

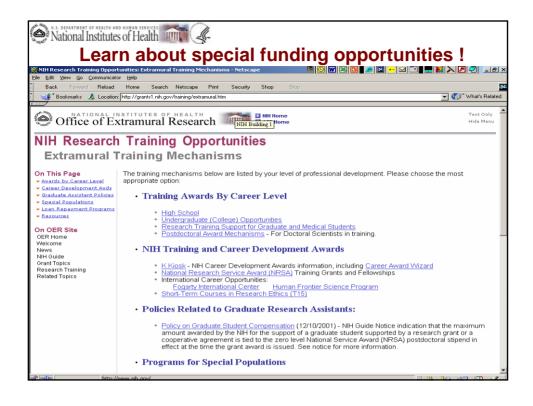
- Announces NIH Scientific Initiatives
- Provides NIH Policy and Administrative Information
- Available on the NIH Web Site: http://www.nih.gov http://grants.nih.gov/grants/guide/index.html









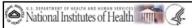






# Program Announcements are very important for you

- Invites grant applications in a given research area
- May describe new or expanded interest in a particular extramural program
- May be a reminder of a continuing interest in a particular extramural program
- Generally has no funds set aside
- Applications reviewed in CSR along with unsolicited grant applications



## Requests for Applications (RFA) are very important for you

- Announcement describing an institute initiative in a well-defined scientific area
- Invitation to submit research grant applications for a one-time competition on a specific topic
- <u>Set-aside of funds for a certain number of awards</u>
- Applications generally reviewed within the issuing institute



#### **Selected Sites of Interest**

National Institutes of Health

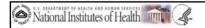
http://www.nih.gov

 Office of Extramural Research http://www.nih.gov/grants/oer.htm

Grants Policy

http://www.nih.gov/grants/policy/policy.htm

 NIH Study Section Rosters http://era.nih.gov/roster/index.cfm



- Office of Extramural Research: Grants Page http://grants1.nih.gov/grants/index.cfm
  - Center for Scientific Review

http://www.csr.nih.gov

•Referral and Review

http://www.csr.nih.gov/refrev.htm

•Overview of Peer Review Process in CSR http://www.csr.nih.gov/review/peerrev.htm

•NIH Peer Review Notes http://www.csr.nih.gov/prnotes/prnotes.htm



#### Office of Extramural Research

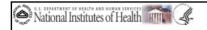
 Handles requests for grant applications, program guidelines, general information on grant applications and review policy

> Office of Extramural Research National Institutes of Health 6701 Rockledge Drive, Suite 6095 Bethesda, Maryland 20892-7910

**PHONE**: 301-435-0714 **FAX**: 301-480-0525

e-mail: grantsinfo@nih.gov



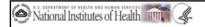


# **Good Grantsmanship**

\*Knowing + Understanding

- What to do
- How to do it
- When to do it
- What to do when things don't go as planned
- \*Being willing to do what is needed
- \*Doing it- doing what is needed

**Understanding Peer Review** 



### Thank You

http://ora.stanford.edu/ora/ratd/nih\_04.asp