1. The handout material is intended to serve as a reference resource for you when you are working on your application

2. The handout contains more information than I will cover in my presentations including Websites, Important policies, Instructions to Reviewers, How to Write a Grant Manual

3. Information that is important is repeated to remind you that it is important

4. You are responsible for reading, learning and making the handout material part of you
Anthony M. Coelho, Jr., Ph.D.
Review Policy Officer

Previous Experience:
Scientific Review Administrator and
Chief - Clinical Studies and Training
Scientific Review Group - NHLBI 7 years
Peer Reviewer 12 years
Funded Investigator 18 years

• NIH Peer Review Process based on Laws
• NIH Peer Review Practices based on Study Section Culture
• My objective is to help you understand both

Most biomedical research in the United States is supported by the Federal Government, and primarily by the National Institutes of Health (NIH)
NIH 2003 Budget
27+ Billion

25+ Billion for Extramural Research
i.e. money for your research

Applying for Funding
Offices at NIH

The wrong way to request funds

Response to the wrong form of request
Elements of Grant Success

Good Ideas
Good Timing
Good Presentations
Good Reviewers
Good Luck
Good Grantsmanship

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

Understanding NIH Peer Review
Rule #1

STUDY SECTIONS DO NOT FUND!

INSTITUTES FUND!

Rule #2

You must satisfy the needs of reviewers and the needs of the funding agency

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!
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

Second Level of Review

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

REVIEW PROCESS FOR NIH RESEARCH GRANTS

1. Principal Investigator Initiates Research Idea
2. Conducts Research
3. Allocates Funds $$
4. Submits application
5. School or Other Research Center (CFR)
6. Assign to IC and IRG
7. Review for Scientific Merit
8. Institute
9. Evaluate for Relevance
10. Recommends Action
11. Institute Director Takes final action for NIH Director

Grant Application Receipt and Assignment
Applications Submitted to NIH

• Approximately 50,000 grant applications are submitted to NIH each year,
• 25-30% are funded
• Competing grant applications are received for three review cycles per year

Typical Timeline for a New Individual Research Project Grant Application (R01)

There are three overlapping cycles per year:

<table>
<thead>
<tr>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Cycle 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit in</td>
<td>February</td>
<td>June, October</td>
</tr>
<tr>
<td>Review in</td>
<td>June, October</td>
<td>February</td>
</tr>
<tr>
<td>Council in</td>
<td>September</td>
<td>January, May</td>
</tr>
<tr>
<td>Earliest award</td>
<td>December</td>
<td>April, July</td>
</tr>
</tbody>
</table>

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

* RFA and RFP dates defined in the solicitations

** ALWAYS check with Institutes to verify dates
What Happens To Your Application When It Arrives at NIH

**Center for Scientific Review (CSR)**
Focal Point for Initial Review at NIH

- 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
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.

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:

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

Assignment to Institutes

Applications are referred to an Institute or Center as the potential funding component:

• Assignment is based on a match between the research proposed and the overall mission of the Institute or Center
• Where applications are appropriate for more than one institute or Center, multiple assignments are made
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 http://era.nih.gov/roster/index.cfm to learn about study sections – their scientific mission and their scientific membership)

Assignment to Study Sections (cont)

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.)

Peer Review of NIH Support Mechanisms

Who Reviews What?

<table>
<thead>
<tr>
<th>CSR</th>
<th>Institutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Project Grant (R01)</td>
<td>Program Project Grant (P01)</td>
</tr>
<tr>
<td>Postdoctoral Fellowship (F32)</td>
<td>Center Grant (P30, P50, P60)</td>
</tr>
<tr>
<td>Senior Fellowship (F32)</td>
<td>Institutional Fellowship (T32)</td>
</tr>
<tr>
<td>Fogarty International Center Fellowship (F05, F06)</td>
<td>Academic Career Award (K07)</td>
</tr>
<tr>
<td>Short-Term Training (T35)</td>
<td>Mentored Clinical Scientist Development Award (K08)</td>
</tr>
<tr>
<td>Small Business Grants (R41, R42 R43, R44)</td>
<td>Conference Grant (R13)*</td>
</tr>
<tr>
<td>Academic Research Enhancement Award (R15)</td>
<td>Marc Fellowships (F34, F36, T34)</td>
</tr>
<tr>
<td>Biomedical Research Support</td>
<td>Minority Biomedical Support Grant (S16)</td>
</tr>
<tr>
<td>Shared Instrumentation Grant (S10)</td>
<td>Resource Grant (P40, P41, R24, R26, R28)</td>
</tr>
<tr>
<td></td>
<td>RFA - Request for Applications R&amp;D - Contracts</td>
</tr>
</tbody>
</table>
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

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

Peer Review 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
Center for Scientific Review
Example of Varied Expertise on a Sample Study Section

Surgery, Anesthesiology and Trauma Study Section
Selected Areas of Competence of Members

- 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

Study Section 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
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 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

• Significance: 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?
• Investigator: Is the investigator appropriately trained?
• Environment: Does the scientific environment contribute to the probability of success? Are there unique features of the scientific environment?
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?

* "Risks" include the possibility of physical, psychological, or social injury resulting from research.

Areas of exemption

Research Involving Human Subjects

Research and Demonstration Projects Regarding Certain Public Benefit or Service Programs

- 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

- Educational 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

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

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?

Animal Welfare

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
  Can not change priority score
• 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
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
Learn the mission of the study section!
Learn the membership of the study section!

Learn about special funding opportunities!

Learn about special funding opportunities!
Program Announcement

- 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)

- 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
- Set-aside of funds for a certain number of awards
- 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
- NIH Study Section Rosters
  http://era.nih.gov/roster/index.cfm
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

NAH GRANT$

Formula for Grant Success
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

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Thank You