

Peer Review of NIH Research Grant Applications

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

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

responsible for:

- developing and implement regulations, policies, procedures, methods, and guidance documents, governing NIH extramural review functions
- ensuring standard approaches to the peer review of grants, cooperative agreements and Research and Development contracts.



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**



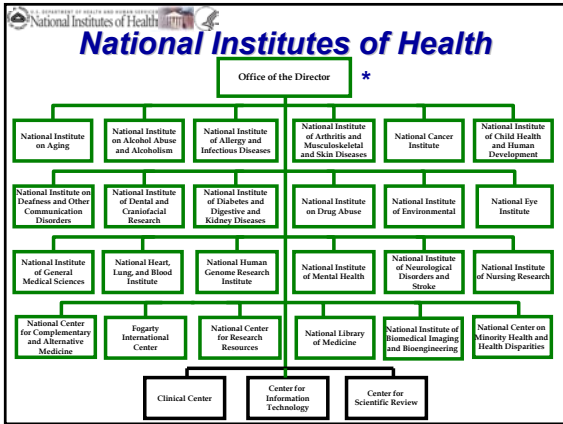
- **NIH Peer Review Process based on Laws**
- **NIH Peer Review Practices based on Study Section Culture**
- **My objective is to help you understand both**



National Institutes of Health



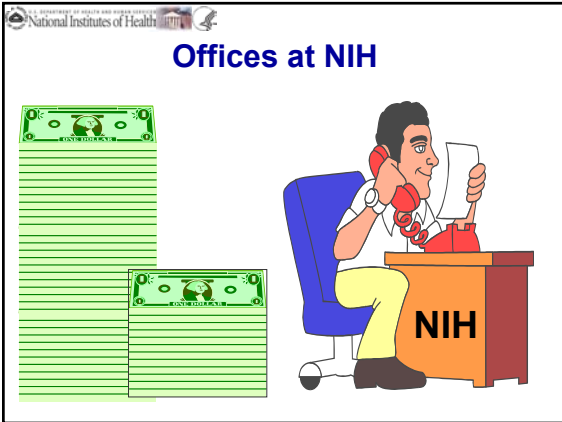
Most biomedical research in the United States is supported by the Federal Government, and primarily by the National Institutes of Health (NIH)

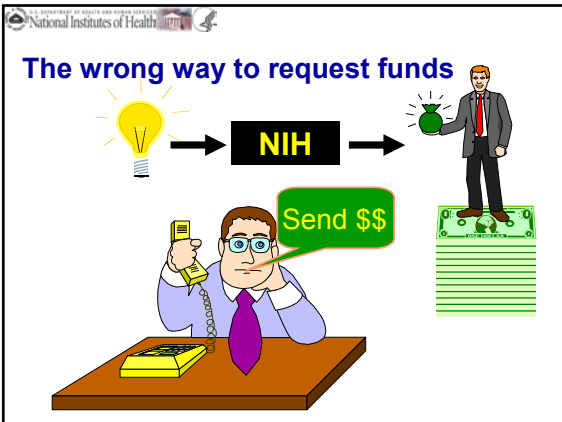


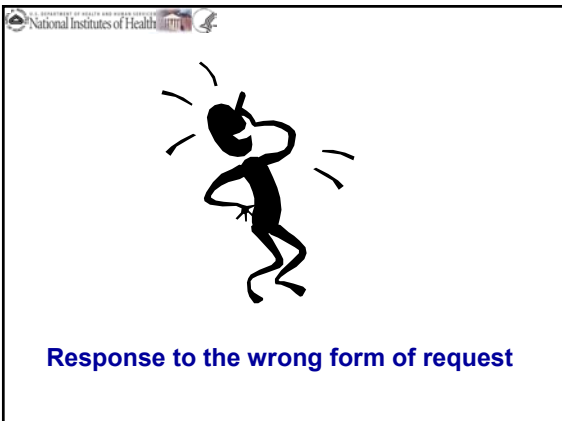
NIH 2003 Budget
27+ Billion

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

Applying for Funding







National Institutes of Health

Correct Way to request Funds




National Institutes of Health

PHS Research Grant Application Kit (form PHS 398)

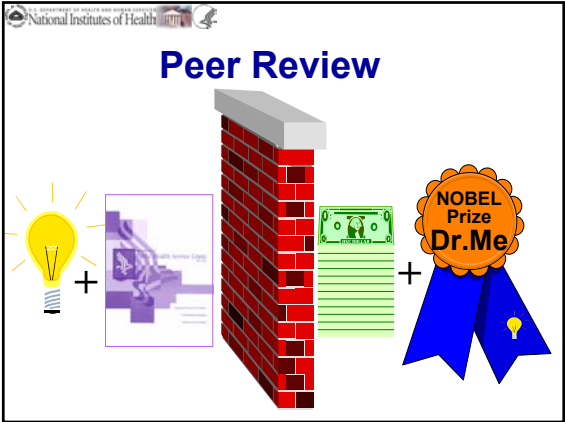
Electronic Forms and Instructions

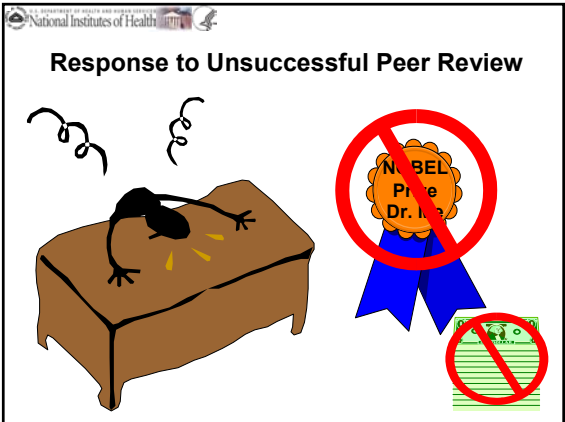


National Institutes of Health

Great Expectations









Elements of Grant Success



Good Ideas



Good Reviewers



Good Timing



Good Luck



Good Presentations



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

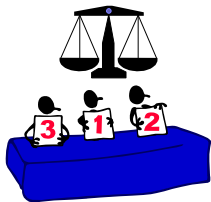


*Being willing to do what is needed

*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

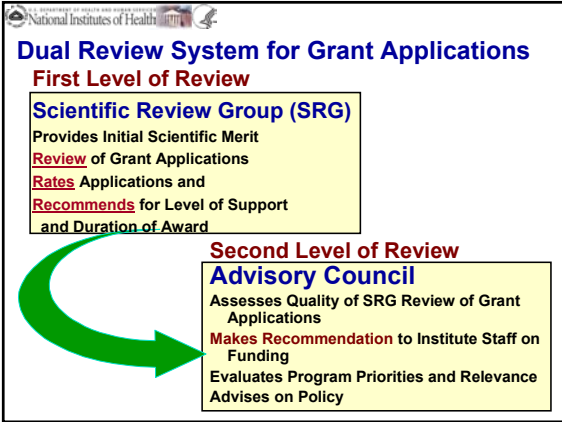


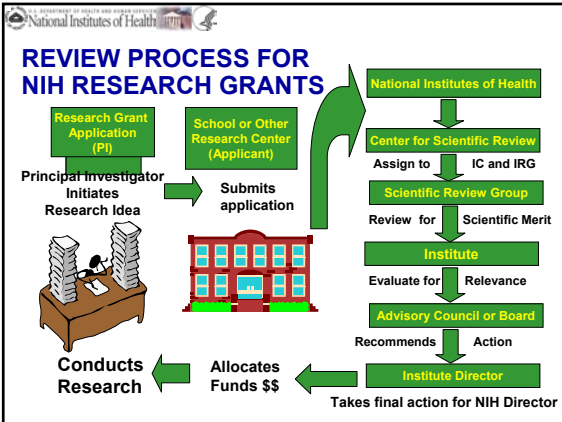
Scientific and Technical Merit

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!





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:

	<u>Cycle 1----</u>	<u>Cycle 2----</u>	<u>Cycle 3----</u>
-Submit in	February	June,	October
-Review in	June	October,	February
-Council in	September	January,	May
-Earliest award	December	April,	July



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**
????

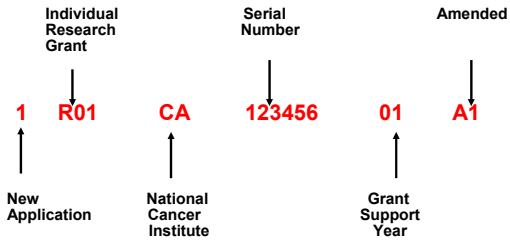


Center for Scientific Review (CSR)
Focal Point for Initial Review at NIH

- 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



Sample Application Number





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.



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 ?

CSR	Institutes
Research Project Grant (R01)	Program Project Grant (P01)
Postdoctoral Fellowship (F32)	Center Grant (P30, P50, P60)
Senior Fellowship (F32)	Institutional Fellowship (T32)
Fogarty International Center Fellowship (F05, F06)	Academic Career Award (K07)
Short-Term Training (T35)	Mentored Clinical Scientist Development Award (K08)
Small Business Grants (R41, R42, R43, R44)	Conference Grant (R13)*
Academic Research Enhancement Award (R15)	Marc Fellowships (F34, F36, T34)
Biomedical Research Support Shared Instrumentation Grant (S10)	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?

- **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

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**



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

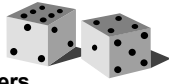
- Some charter members; some temporary members
- Scientists with appropriate expertise
- High professional profiles
- Dependable, reasonable, open minded



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.

SIGNATURES

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?
- [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

Animal Welfare

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
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>
<http://grants.nih.gov/grants/guide/index.html>

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
<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



The graphic features the text "NIH GRANT\$" in large blue letters with a green dollar sign. Below it is the phrase "Formula for Grant Success" in red. The graphic is composed of several icons: a glowing lightbulb, a clock, a group of diverse people, a horseshoe, a man in a suit talking on a mobile phone, and a man in a suit holding a money bag. These icons are arranged in a sequence separated by plus signs, leading to an equals sign and a stack of money labeled "NIH\$".

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
