



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

Experience:

•NIH Review Policy Officer

8 years

•Chief - Clinical Studies and Training Section NIHBI and

7 years

Scientific Review Administrator

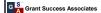
•Peer Reviewer

12 years

•Funded Investigator

18 years

(NIH, DOE, EPA and Private Sector Funding)



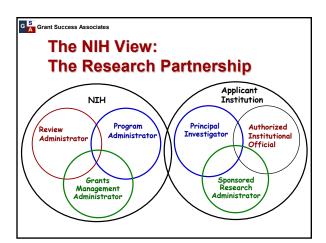
Important Things to Know:

- 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

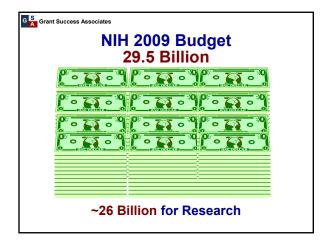


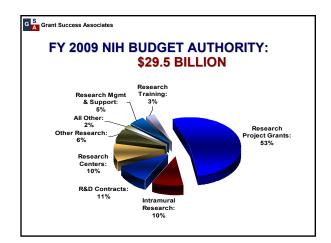
Important Things to Know:

- 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

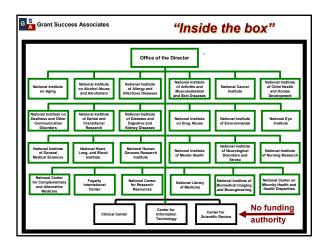


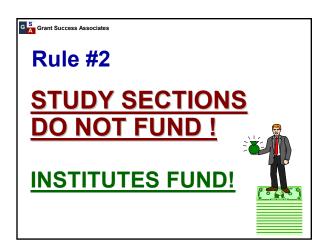


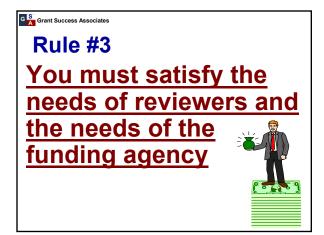


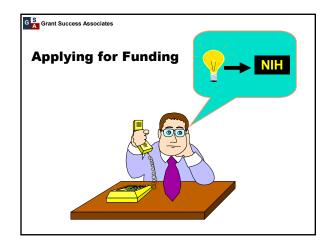


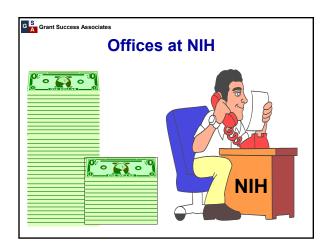


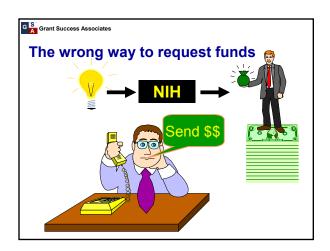


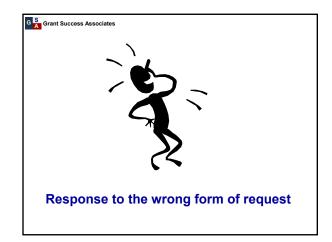


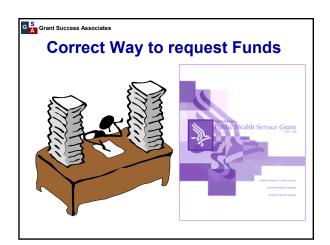


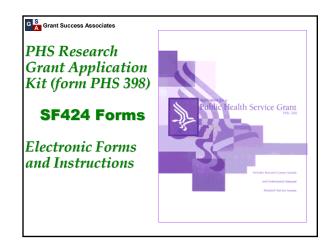


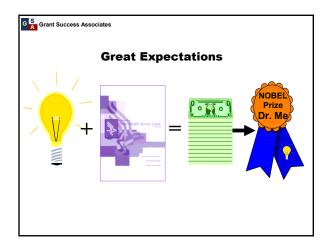


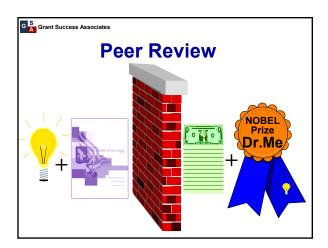






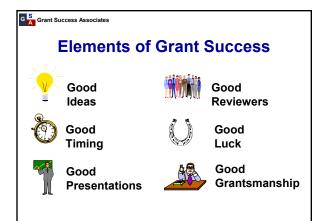










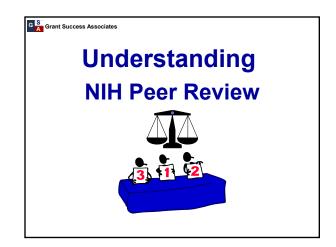


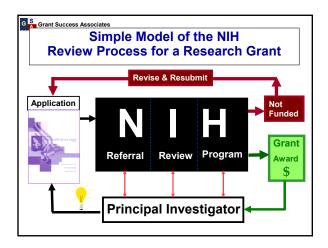


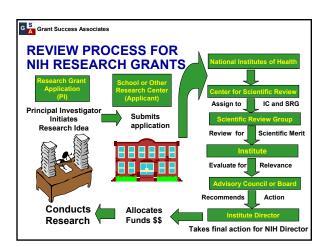
















1st Level Review



- Standing study section typically has 12-24 members
- 3 face-to-face meetings each year
- Review 60 100 applications at each meeting

View the "Mock Study Section" video today and tomorrow



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 75,000+ grant applications are submitted to NIH each year,
- 10-20% are funded (Institute specific)
- Competing grant applications are received for three review cycles per year





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

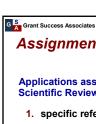


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Center for Scientific Review (CSR)

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 $\underline{\text{http://era.nih.gov/roster/index.cfm}}$

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)

Academic Career Award (K07) Mentored Clinical Scientist Development Award (K08) Conference Grant (R13)* Minority Biomedical Support Grant (S06) Resource Grant (P40, P41, R24, R26, R28) **RFA - Request for Applications**

Program Project Grant (P01) Center Grant (P30, P50, P60) Institutional Fellowship (T32) Marc Fellowships (F34, F36, T34) R&D - Contracts

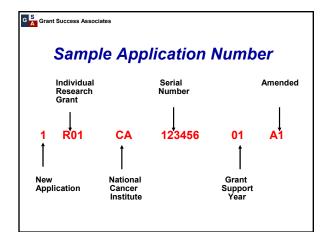


WHO/WHAT DETERMINES WHICH GROUP REVIEWS THE APPLICATION?

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.

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Assignment Notification Letter (continued)	
Principal Investigator: Sample Pamela	
Assignment Number: 2 R01 HL12345 - 12A1	
<u>Dual Assignment</u> : NS	
Scientific Review Group: Epidemiology and Disease Control Subcommittee 2 SS (EDC2)	
1	
A roster of the membership of this Scientific Review Group located on the following website:	
http://era.nih.gov/roster/index.cfm	
S Grant Success Associates	1
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	
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Assignment Notification Letter (continued)	
Assignment Nouncation 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)

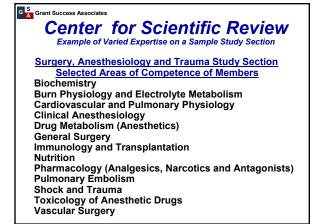
- when the subject matter does not fit into any study section, or
- when assignment of an application to the most appropriate study section would create a conflict of interest, or
- Special Mechanisms (RFA, Fellowships, SBIRs, AREAS, etc.)

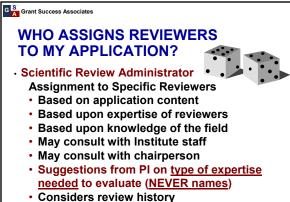


Study Sections at NIH

- Study Sections are managed by a Scientific Review Administrator (SRA/SRO) 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









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

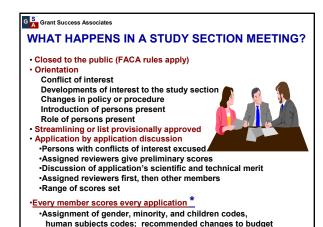
This will certify that in the review of applications and proposals by (study section) on (date), I did not participate in the evaluation of any grant or fellowship applications from (1) any organization, institution or university system in which a financial interest exists to myself, spouse, parent,child, 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 IS STREAMLINING?

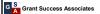
Process by which reviewers judge which applications are in the lower half of those assigned for review.

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

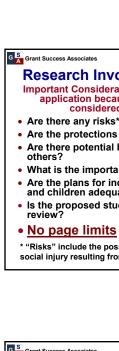
- Significance: Does the study address an important problem? How will scientific knowledge be advanced?
- Approach: Are design and methods well-developed and appropriate? Are problem areas addressed?
- Innovation: Are there novel concepts or approaches? Are the aims original and innovative?
- Investigator: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

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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 alms 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?
- Networking to 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)?
- S. 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?

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

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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

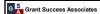


Research Involving Children

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

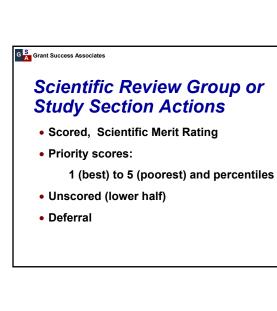
Important Considerations

- 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?



PHS424

- Description of proposed use of animals in the work outlined in Research Design and Methods section. Identify species, strains, ages, sex, and numbers of animals used
- Justify use of animals, choice of species, and numbers used. If in short supply, costly, or used in large numbers, provide additional rationale for their selection and numbers.
- Provide information on the veterinary care of the animals involved.
- 4. Describe procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe use of analgesic, anesthetic, and tranquillizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
- Describe any method of euthanasia used and reasons for selection. State whether method is consistent with recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.





Scientific Review Group or Study Section Actions

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



What do the Scores Mean?

Scored Application

1.0-1.5 (100 - 150) OUTSTANDING 1.5-2.0 (150 - 200) EXCELLENT

2.0-3.0 (200 - 300) GOOD

3.0-5.0 (300 - 500) BELOW AVERAGE

STREAMLINED

Unscored APPLICATIONS

3.0-5.0 (300 to 500) BOTTOM HALF



New Scoring System

- effective for all applications submitted after January 25, 2009
- The new scoring system will utilize a 9-point rating scale (1 = exceptional; 9 = poor).

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-024.html



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
- 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



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)

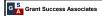


REVISE & RESUBMIT Do Not Appeal Review Outcome

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)
- **Council Accepts Appeal: Original Application** be sent to a new Study Section but without the Letter of Appeal (bad outcome)

Grant Success Associates	Timeline C	onsequen	ces
	Best Way	Revision	Appeal
Submit	Feb 08	Feb 08	Feb 08
Review	June 08	June 08	June08
Council	Sept 08	Sept 08	Sept 08
Earliest award	Dec 08		
Review 2		'	Oct 08
Council 2			Jan 09
Earliest Resubmission		March 09	
Earliest Award			A6K 09
Review 2		June 09	
Earliest Resubmission			July 09
Council 2		Sept 09	
Review 3			Oct 09
Earliest Award		Dec 09	
Council			Feb 10
Earliest Award			June 10



What Determines Which Awards Are Made?

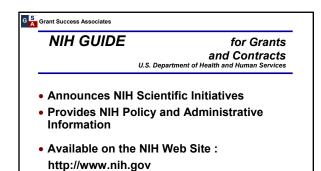
- Scientific merit +
- Program Considerations +
- Availability of funds



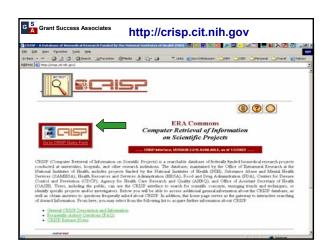
You do not want a reviewer to make this comment about your application:

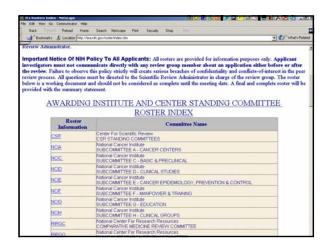
"This application is characterized by ideas that are both original and scientifically important. Unfortunately the ideas that are scientifically important are not original and the ideas that are original are not scientifically important."

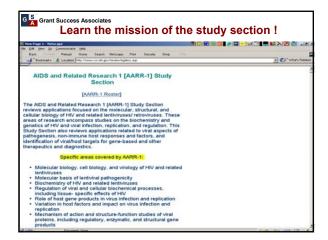
G S Grant Success Associates	
You do not want a reviewer to make this comment about your application:	
"In addition to proposing a	
research design that is a fishing expedition,	
the applicant also proposes to use every type of bait and piece of	
tackle ever known to mankind."	
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<u> </u>	
The research that you	
propose in your	
application must be innovative and focused	
G S Grant Success Associates]
NIH Information Sources	

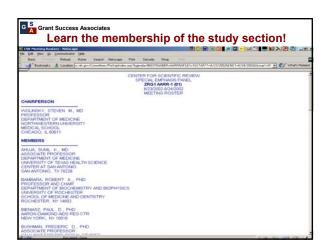


http://grants.nih.gov/grants/guide/index.html







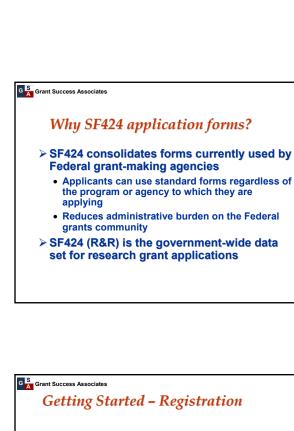












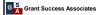
Grants.gov Registration

- One-time only registration good for electronic submission to all Federal agencies
- Registration on Grants.gov required only for institutions
 - Detailed instructions at: http://grants.gov/GetStarted
 - Grants.gov registration requires institutions
 - Obtain a Data Universal Numbering System (DUNS) number if you don't already have one.

It is critical for institutions to begin this registration process at least 4 weeks before applications are due!



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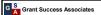
Where to find more information

- NIH eRA's Electronic Receipt Web Site: http://era.nih.gov/ElectronicReceipt/
 - Note: An expanded presentation is posted on this website for institutions to use to help spread the word about these important changes.
- NIH Guide Notices: http://grants1.nih.gov/grants/guide/index.html



Where to go for help

- Questions on NIH plan for electronic receipt
 - NIH GrantsInfo.gov
 - E-mail: grantsinfo@nih.gov
- NIH eRA Commons registration and questions
 - Support Page: http://era.nih.gov/commons/index.cfm
 - Help Desk
 - E-mail: commons@od.nih.gov
- Phone: 1-866-504-9552 OR 301-402-7469
 Grants.gov registration and submission questions
 - Visit: http://www.grants.gov/CustomerSupport



Other Resources/Links

- Office of Extramural Research Grants Home Page: http://grants.nih.gov/grants/oer.htm
- NIH Guide: http://grants.nih.gov/grants/guide/index.html
- NIH Grants Policy Statement (12/03): http://grants.nih.gov/grants/policy/nihgps 2003/index.htm
- PHS 398 Application (form pgs are PDF-fillable): http://grants1.nih.gov/grants/funding/phs398/phs398.html
- PHS2590 Progress Report (form pgs are PDF-fillable): http://grants.nih.gov/grants/funding/2590/2590.htm



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

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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
- Set-aside of funds for a certain number of awards
- Applications generally reviewed within the issuing institute

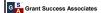


Selected Sites of Interest

- 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 <u>http://era.nih.gov/roster/index.cfm</u>
- Grant Application Basics http://grants.nih.gov/grants/grant_basics.htm http://grants.nih.gov/grants/grants_process.htm



- 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



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