NIH Center for Scientific Review

NIH Peer Review
"How is your Application Reviewed"

Mark Rubert, Ph.D.

Scientific Review Officer

NIH SGM Regional Seminar

May 12, 2018
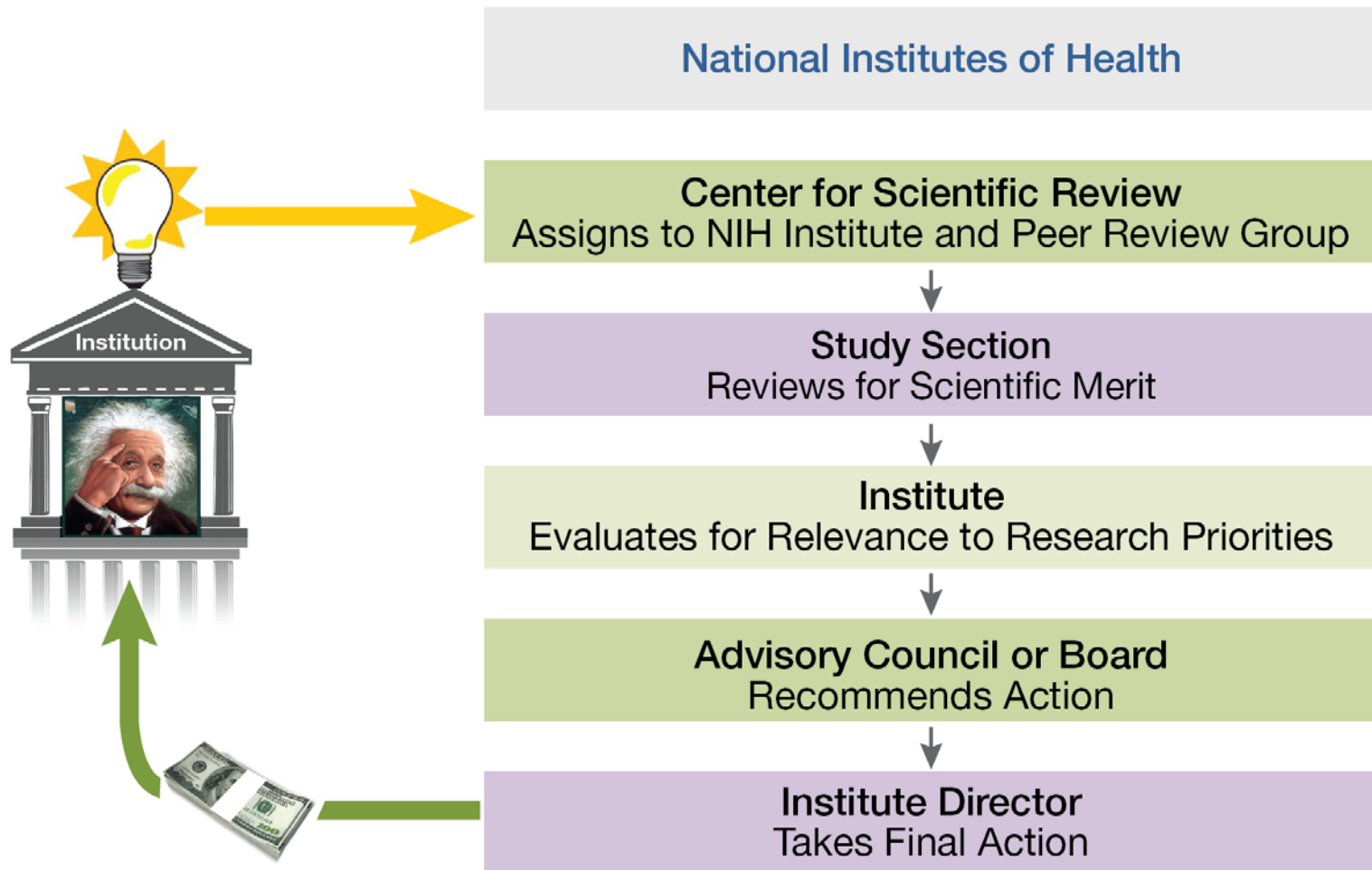
NIH Peer Review System for Grant Applications

First Level of Review
Scientific Review Group
(Study Section)

Second Level of Review
NIH Institute/Center Council

Peer Review and Funding of NIH Grant Applications

Center for Scientific Review

Your Application Goes to the NIH Center for Scientific Review (CSR)

Focal Point for Initial Review at NIH

- Receives all NIH applications
- Refers them to NIH Institutes/Centers and to scientific review groups
- Reviews majority of grant applications for scientific merit

NIH Center for Scientific Review

CSR Mission

To see that NIH grant applications receive fair, independent, expert, and timely reviews – free from inappropriate influences – so NIH can fund the most promising research.

CSR Peer Review – Fiscal Year 2016

- 95,000 applications received

- 61,000 applications reviewed

- 18,000 reviewers

- 247 Scientific Review Officers

- 1,600 review meetings

CSR Web Site

- About CSR

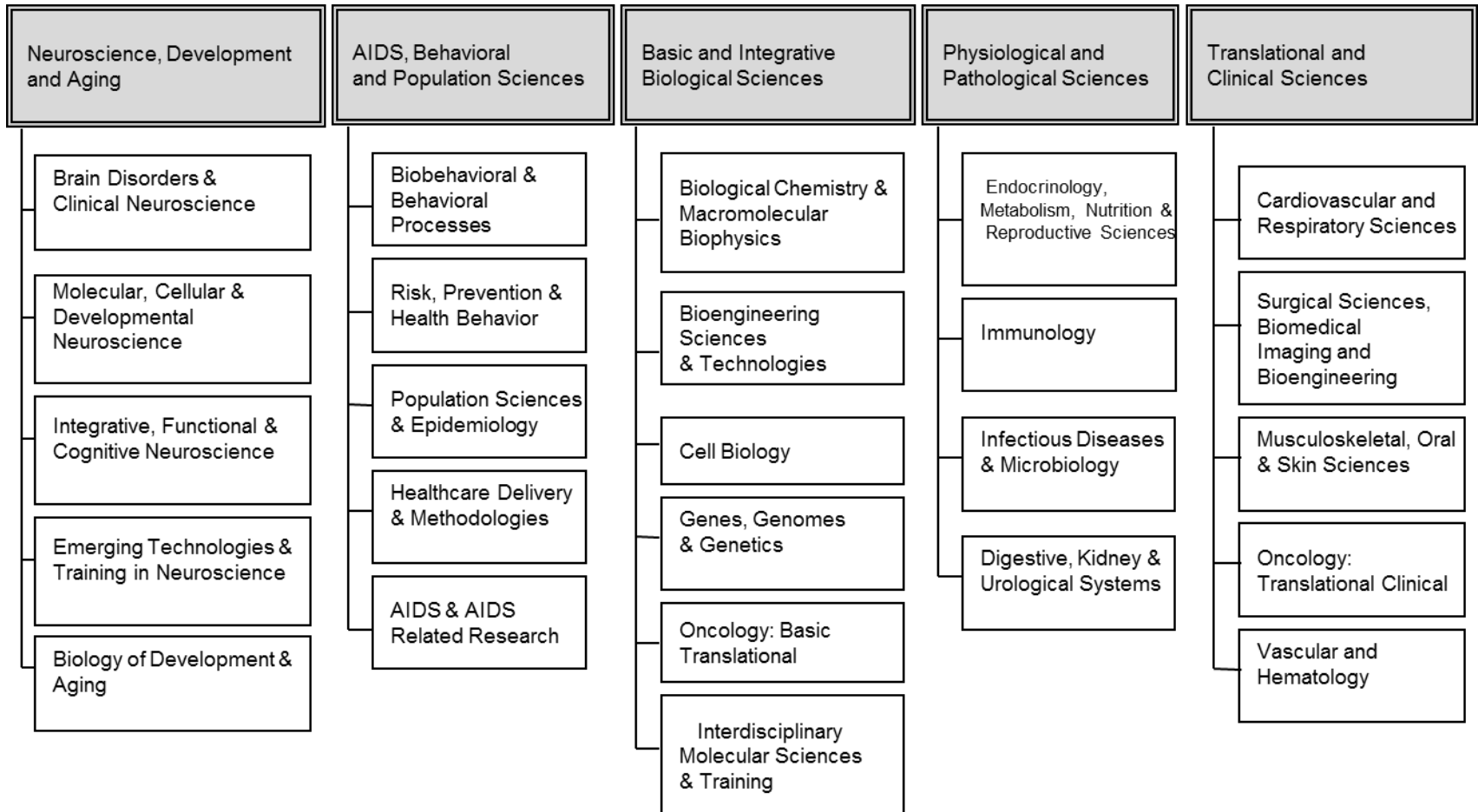- Applicant Resources

- Study Sections

- Rosters and Meetings

http://www.csr.nih.gov

Divisions and Integrated Review Groups (IRGs)

Neuroscience, Development and Aging	AIDS, Behavioral and Population Sciences	Basic and Integrative Biological Sciences	Physiological and Pathological Sciences	Translational and Clinical Sciences
Brain Disorders & Clinical Neuroscience	Biobehavioral & Behavioral Processes	Biological Chemistry & Macromolecular Biophysics	Endocrinology, Metabolism, Nutrition & Reproductive Sciences	Cardiovascular and Respiratory Sciences
Molecular, Cellular & Developmental Neuroscience	Risk, Prevention & Health Behavior	Bioengineering Sciences & Technologies	Immunology	Surgical Sciences, Biomedical Imaging and Bioengineering
Integrative, Functional & Cognitive Neuroscience	Population Sciences & Epidemiology	Cell Biology	Infectious Diseases & Microbiology	Musculoskeletal, Oral & Skin Sciences
Emerging Technologies & Training in Neuroscience	Healthcare Delivery & Methodologies	Genes, Genomes & Genetics	Digestive, Kidney & Urological Systems	Oncology: Translational Clinical
Biology of Development & Aging	AIDS & AIDS Related Research	Oncology: Basic Translational		Vascular and Hematology
		Interdisciplinary Molecular Sciences & Training		

Division of AIDS, Behavioral and Population Sciences

Integrated Review Groups
Biobehavioral & Behavioral Processes
Risk, Prevention & Health Behavior
AIDS and AIDS Related Research
Healthcare Delivery & Methodologies
Population Sciences and Epidemiology

AIDS Clinical Studies and Epidemiology

AIDS Discovery and Development of Therapeutics

AIDS Immunology and Pathogenesis

AIDS Molecular and Cellular Biology

AIDS-Associated Opportunistic Infections and Cancer

Behavioral and Social Consequences of HIV/AIDS

Behavioral and Social Science Approaches to Preventing HIV/AIDS
NeuroAIDS and other End-organ Diseases
HIV/AIDS Vaccines

Help Your Application Get to the Right Study Section

Find a Study Section

Applications are reviewed in Study Sections (Scientific Review Group, SRG). Integrated Review Groups (IRGs) are clusters of Study Sections based on scientific discipline.

| Enter Search Keywords | Go |

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

Help Your Application Get to the Right Study Section

Integrated Review Group

Help Your Application Get to the Right Study Section

Study Section

Assisted Referral Tool (Art)

Enter application text and get a list of relevant study sections

https://art.csr.nih.gov

Assignment Request Form (ARF)

The ARF replaces many functions of the cover letter.
Use it to:

- Make assignment requests
- Identify potential conflicts of interest
- List areas of expertise needed to evaluate the application

You should never suggest specific reviewers

Assignment Request Form (ARF)

Requests for IC assignment ➤

Requests for review group assignment ➤

Identify conflicts ➤

Suggest expertise ➤

Cover Letter

You can use a cover letter to:

- Explain why your application is late
- Provide notice of plans to submit a video
- Identify your project as generating large-scale genomic data
- Provide pre-approvals ($500k, conference grants)

You should NOT use a cover letter to:

- Make assignment requests (use the ARF!)
- Suggest specific reviewers (never do this!)

Applications Are Assigned to:

- **Institutes or Centers based on─**
  - Overall mission and guidelines of the Institute or Center
  - Specific programmatic mandates and interests of the Institute or Center

- **Integrated Review Groups based on─**
  - Specific review guidelines for each Integrated Review Group (IRG)

Assignment to CSR Study Sections

Within an IRG, applications are assigned to:

Standing Study Sections

- When subject matter of application matches the referral guidelines for the study section or

Special Emphasis Panels (SEPs)

- When the subject matter does not fit into any study section
- When assignment of an application to the most appropriate study section creates a conflict of interest
- When certain types of grants are sought (e.g., fellowships, SBIRs, AREAS)

How NOT to Submit a Late Application

Start Early!

- Application must be accepted **TWICE**: Grants.gov and NIH

Check eRA Commons for your submitted application
(e-mails are sent but can be caught in SPAM filters)

- High volume at deadlines slows processing/validation time
- On time application = submitted error-free by 5 PM local time on due date
- Errors cause rejection – Warnings are error-free and accepted
- **No error correction window that extends deadline**

Preparing an Application

There is no grantsmanship that will turn a bad idea into a good one, but………

There are many ways to disguise a good one.

William Raub
Past Deputy Director, NIH

Electronic Application Process

Prepare to Apply & Register	→	Find Opportunity	→	Prepare Application	→	Submit, Track & View
• **Register with Grants.gov & eRA Commons**		• **Submit in response to Funding Opportunity Announcement (FOA)**		• **Follow Application Guide & Instructions**		• **Submit via your organizational representative** • **Use eRA Commons to view & track**
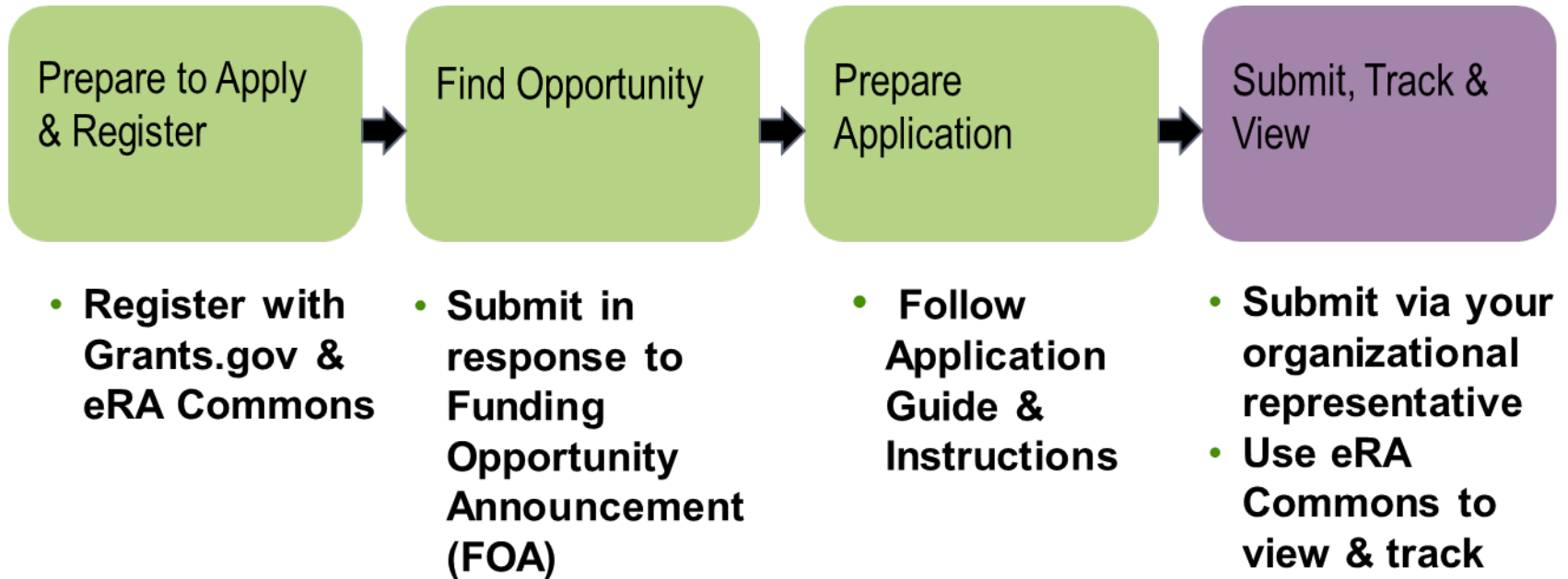
When Preparing an Application

- Read instructions
- Never assume that reviewers will know what you mean
- Refer to pertinent literature
- Don't overstate the significance of your research
- State rationale of proposed investigation
- Include well-designed tables and figures
- Present an organized, lucid write-up
- Don't be overly ambitions
- Obtain pre-review from colleagues at your organization

Insider's Guide to Peer Review for Applicants:
http://www.csr.nih.gov/applicantresources/insider

Alignment

Criteria	Application
Significance	Research Strategy a. Significance
Investigator(s)	Biosketch Personal Statement
Innovation	Research Strategy b. Innovation
Approach	Research Strategy c. Approach
Environment	Resources Environment

NIH Center for Scientific Review

What Reviewers Look for in Applications

- Significance and impact

- Exciting ideas

- Clarity

- Ideas they can understand -- Don't assume too much

- Realistic aims and timelines -- Don't be overly ambitious

- Brevity with things that everybody knows

- Noted limitations of the study

- A clean, well-written application

Insider's Guide to Peer Review for Applicants:
http://www.csr.nih.gov/applicantresources/insider

NIH Center for Scientific Review

Common Problems in Applications

- Lack of new or original ideas
- Absence of an acceptable scientific rationale
- Lack of experience in the essential methodology
- Questionable reasoning in experimental approach
- Uncritical approach
- Diffuse, superficial, or unfocused research plan
- Lack of sufficient experimental detail
- Lack of knowledge of published relevant work
- Unrealistically large amount of work
- Uncertainty concerning future directions

The Study Section Meeting

Peer Review: The Study Section Meeting

- CSR Study Sections are managed by a Scientific Review Officer (SRO) who is a doctoral-level professional, whose scientific background is close to the focus of the study section.

- Each CSR standing study section has 12-25 regular members who are from the scientific community.

- Temporary members are recruited as needed.

- About 60-100 applications are normally reviewed at each study section meeting.

Before the Study Section Meeting

- Each application is assigned to 3 or more reviewers 5-6 weeks in advance

- Reviewers assess each application by providing:
  - A preliminary Overall Impact score
  - Criterion Scores for each of the 5 Core Review Criteria
  - A written critique

At the Meeting

Order of Review

- The average of the preliminary Overall Impact score from the assigned reviewers determines the review order
- Discussions start with the application with the best average preliminary Overall Impact score

Clustering of Review

- New Investigator R01 applications are clustered
- Clinical applications & other mechanisms may be clustered (n ≥ 20)

Not Discussed Applications

- About half the applications will be discussed
- Applications unanimously judged by the review committee to be in the lower half are not discussed

Discussions Focus on the Best Applications

- Reviewers typically discuss the top half of the applications

- The panel will discuss any application a reviewer wants to discuss

Review Criteria

5 Core Review Criteria

- **Significance**
- **Investigator(s)**
- **Innovation**
- **Approach**
- **Environment**
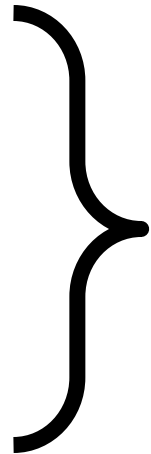
Each scored from 1-9

Overall Impact

Assessment of the likelihood for the project to *exert a sustained, powerful influence on the research field(s) involved*

Scored from 1-9

9-Point Scoring Scale

Impact	Score	Descriptor
High Impact	1	Exceptional
	2	Outstanding
	3	Excellent
Medium Impact	4	Very Good
	5	Good
	6	Satisfactory
Low Impact	7	Fair
	8	Marginal
	9	Poor

Scoring

9-point score scale is used to provide:

- Criterion Scores for each of the 5 core review criteria
- Overall Impact/Priority Score based on but not a sum of the core criterion scores plus additional criteria

All applications receive scores:

- Not discussed applications will receive only initial criterion scores from the three assigned reviewers.
- Discussed applications also receive an averaged overall impact score from eligible (i.e., without conflicts of interest) panel members.

Reviewing Rigor and Transparency
Research Project Grant Applications

Rigor and Transparency Element	Which applications?	Where in the application?	Which Criteria?	What's added to the review criteria?	Affect overall impact score?
Scientific Premise	All	Research Strategy (Significance)	Significance	Is there a strong scientific premise or foundation for the project?	Yes
Scientific Rigor	All	Research Strategy (Approach)	Approach	Are there strategies to ensure a robust and unbiased approach?	Yes
Consideration of Relevant Biological Variables, Such as Sex	Projects with vertebrate animals and/or human subjects	Research Strategy (Approach)	Approach	Are adequate plans to address relevant biological variables, such as sex, included for studies in vertebrate animals or human subjects?	Yes
Authentication of Key Biological and/or Chemical Resources	Project involving key biological and/or chemical resources	New Attachment	Additional review considerations	Comment on plans for identifying and ensuring validity of resources.	No

Four Rigor and Transparency Review Elements
Research Project Grant Applications

Can Affect Your Overall Impact Score!

Rigor and Transparency Element	What's added to the review criteria?	Where in the application?
1. Scientific Premise	Is there a strong scientific premise or foundation for the project?	Research Strategy (Significance)
2. Scientific Rigor	Are there strategies to ensure a robust and unbiased approach?	Research Strategy (Approach)

Four Rigor and Transparency Review Elements
Projects with Vertebrate Animals and/or Human Subjects

Can Affect Your Overall Impact Score!

Rigor and Transparency Element	Where in the application?	What's added to the review criteria?
3. Consideration of Relevant Biological Variables, Such as Sex	Research Strategy (Approach)	Are adequate plans to address relevant biological variables, such as sex, included for studies in vertebrate animals or human subjects?

Research Involving Human Subjects

Important Considerations

- Is the proposed study exempt from human subject review?

- Are there any apparent physical, psychological or social risks to the human subjects?

- Are the protections adequate?

- What are the potential benefits to the subjects and to mankind?

- Are the inclusions of minorities and both genders adequately addressed?

NIH Center for Scientific Review

Clinical Research Involving Human Subjects

Four questions to determine the difference between a clinical study and a clinical trial:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Clinical Research Involving Human Subjects

If the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

Research Involving Children

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

- Child is defined as an individual under age 18

- If children are included, Investigator must address:
  - age range
  - expertise of investigative team
  - facilities
  - sufficient numbers

- If children are not included, must justify exclusion

Inclusion of Women and Minorities

Proposed clinical research must include:

- Plans for the inclusion of minorities and members of both genders, as well as the inclusion of children.

    or

- A clear and compelling justification indicating that inclusion is inappropriate due to the health of the subjects or the purpose of the research.

http://grants.nih.gov/grants/funding/women_min/women_min.htm

NIH〉 Center for Scientific Review

Vertebrate Animal Welfare

Important Considerations
Simplified in 2016: NOT-OD-16-006

- Concise description of the procedures involving vertebrate animals. Identify species, strains, ages, sex, and numbers to be used.

- Justifications that the species are appropriate for the proposed research.

- Description of interventions used in minimizing discomfort, distress, pain and injury.

- Method(s) of euthanasia, if not consistent with American Veterinary Medical Association guidelines (this is provided in supplement form D of the application).

Biohazards

Important Considerations

- Are the necessary special facilities available to protect the environment and research personnel from potentially hazardous conditions?

- Will biohazardous materials be handled appropriately?

- Have employees been trained adequately in safe practices?

Check the Status of Your Application in NIH eRA Commons

Your Summary Statement

- Scores for each review criterion

- Critiques from assigned reviewers

- Administrative notes if any

If your application is discussed, you also will receive:

- An overall impact/priority score and percentile ranking

- A summary of review discussion

- Budget recommendations

Summary Statement

Program Officer

Impact/Priority Score 10-90 range

Percentile in whole numbers

Indicator for Early Stage Investigators

SUMMARY STATEMENT
(Privileged Communication)

PROGRAM CONTACT:
BARBARA CROFT PH.D.
301 496-9531
erastage@mail.nih.gov

Release Date: 04/04/2008
Revised Date: 01/06/2009

Application Number:

Principal Investigator

Applicant Organization:

Review Group: GCMB
Gastrointestinal Cell and Molecular Biology Study Section

Meeting Date: 03/24/2008
Council: MAY 2008
Requested Start: 07/01/2008

RFA/PA: PA01-295
PCC: 2A

Project Title:

SRG Action: Impact/Priority Score: 20
Human Subjects: 10-No human subjects involved
Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Project Year	Direct Costs Requested	Percentile: 29	Estimated Total Cost
1	250,000		291,200
2	250,000		291,200
3	250,000		291,200
4	250,000		291,200
5	250,000		291,200
TOTAL	1,250,000		1,456,000

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

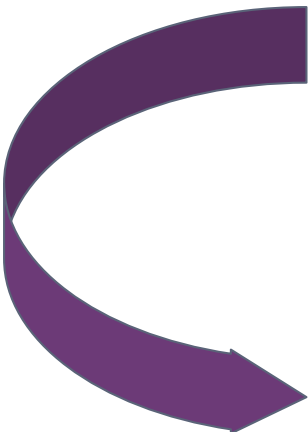EARLY STAGE INVESTIGATOR

NEW INVESTIGATOR

Your Application Was Reviewed
What Do You Do Next?

Visit NIH's Next Steps Website

http://grants.nih.gov/grants/next_steps.htm

CSR and NIH Information Sources
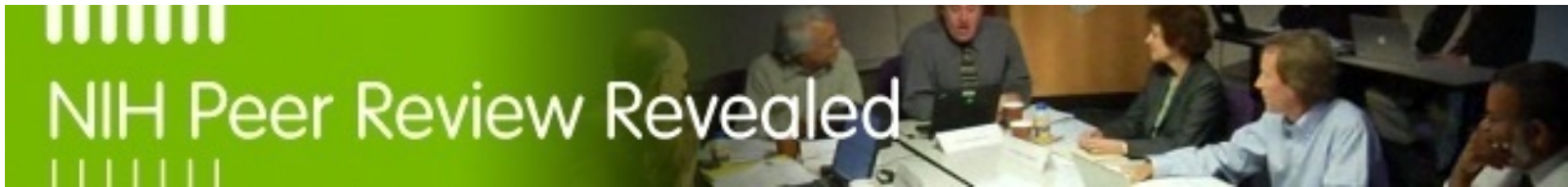
View the Videos

- **NIH Peer Review Revealed**

- **Navigating NIH Peer Review**

- **Jumpstart Your Research Career with CSR's Early Career Reviewer Program**

- **NIH Tips for Applicants**

http://www.csr.nih.gov/video/video.asp

Center for
Scientific Review

Who Can Answer Your Questions?

Before You Submit Your Application

- A Program Officer at an NIH Institute or Center
- Scientific Review Officer

After You Submit

- Your Scientific Review Officer

After Your Review

- Your Assigned Program Officer

GrantsInfo: GrantsInfo@nih.gov – 301 435-0714

NIH Peer Review Information on the Web

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

- **Electronic Submission**
  http://era.nih.gov/ElectronicReceipt

Center for Scientific Review: http://www.csr.nih.gov

- **Resources for Applicants**
  http://www.csr.nih.gov/ResourcesforApplicants

- **CSR Study Section Descriptions**
  http://public.csr.nih.gov/StudySections

- **CSR Rosters and Meeting Dates**

  http://public.csr.nih.gov/RosterAndMeetings

Thank You