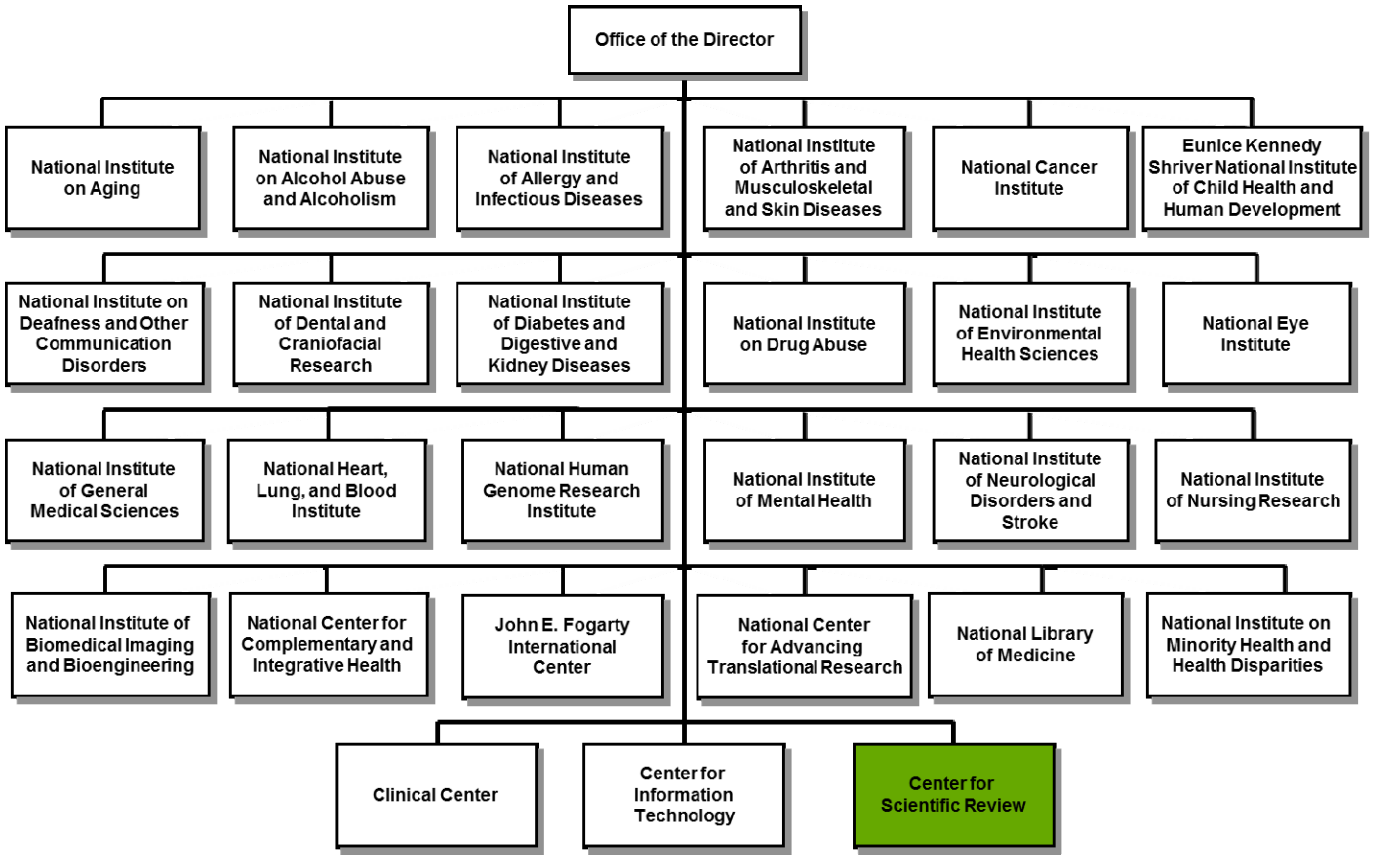
Goals of the Presentation

Familiarization with the NIH Review Process

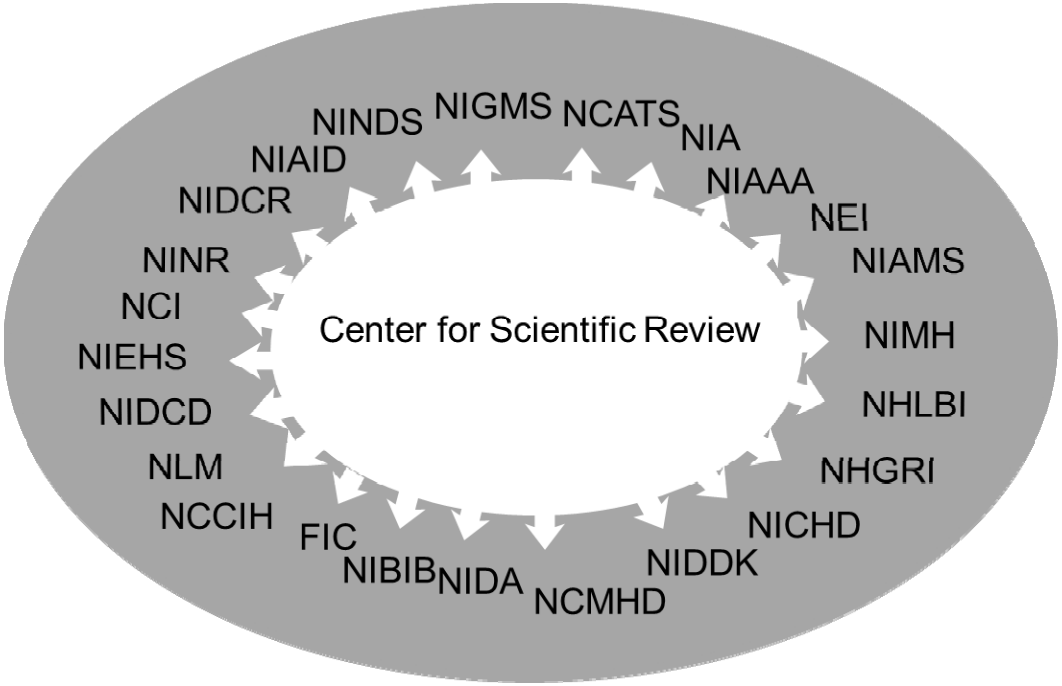
- The life cycle of a Grant Application
- Receipt and Referral Process
- The Study Section
- The Review Process
- Outcome of Review
- Resources

National Institutes of Health

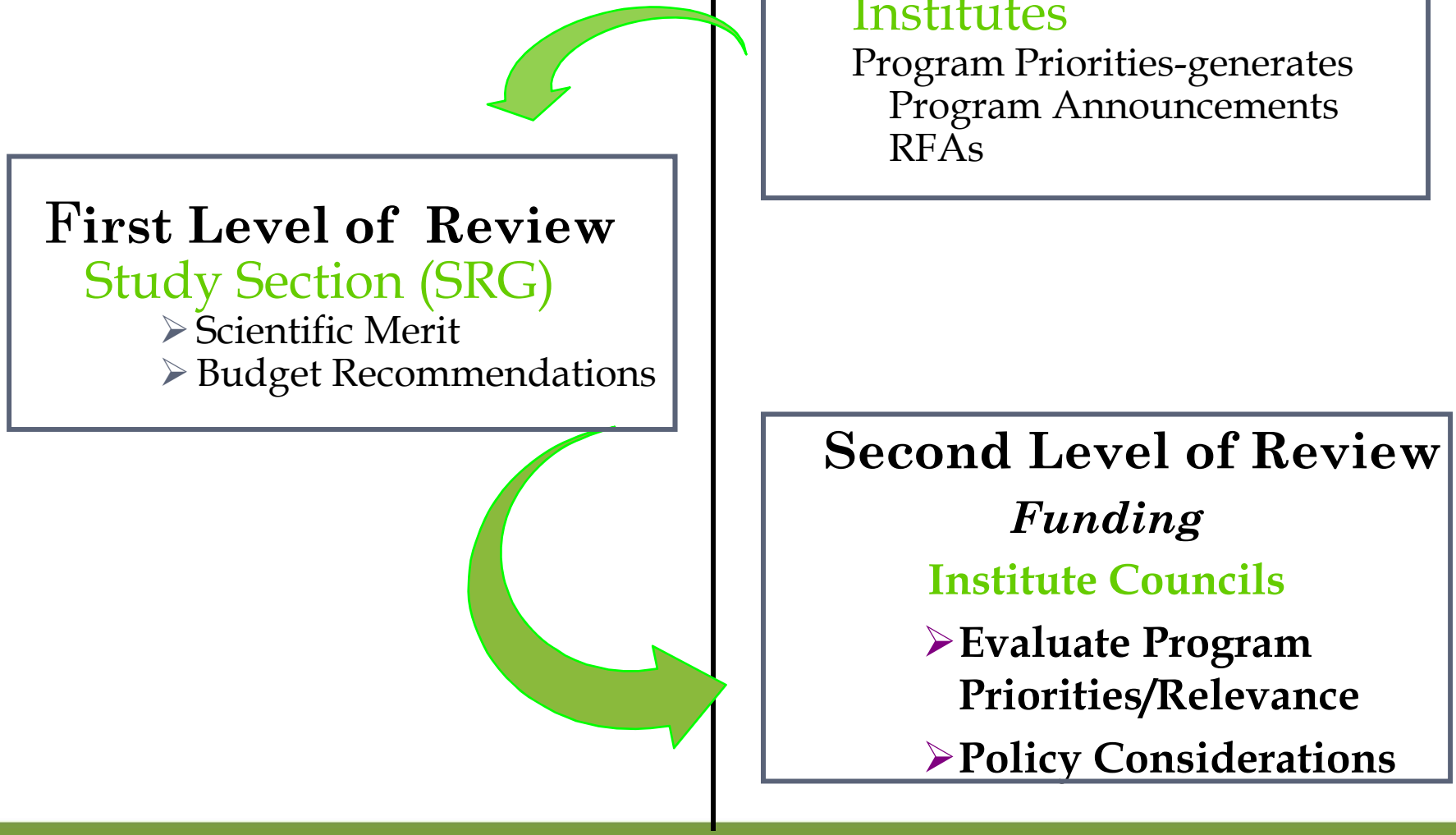
Your Application Could Be Funded by One of 24 NIH Institutes or Centers



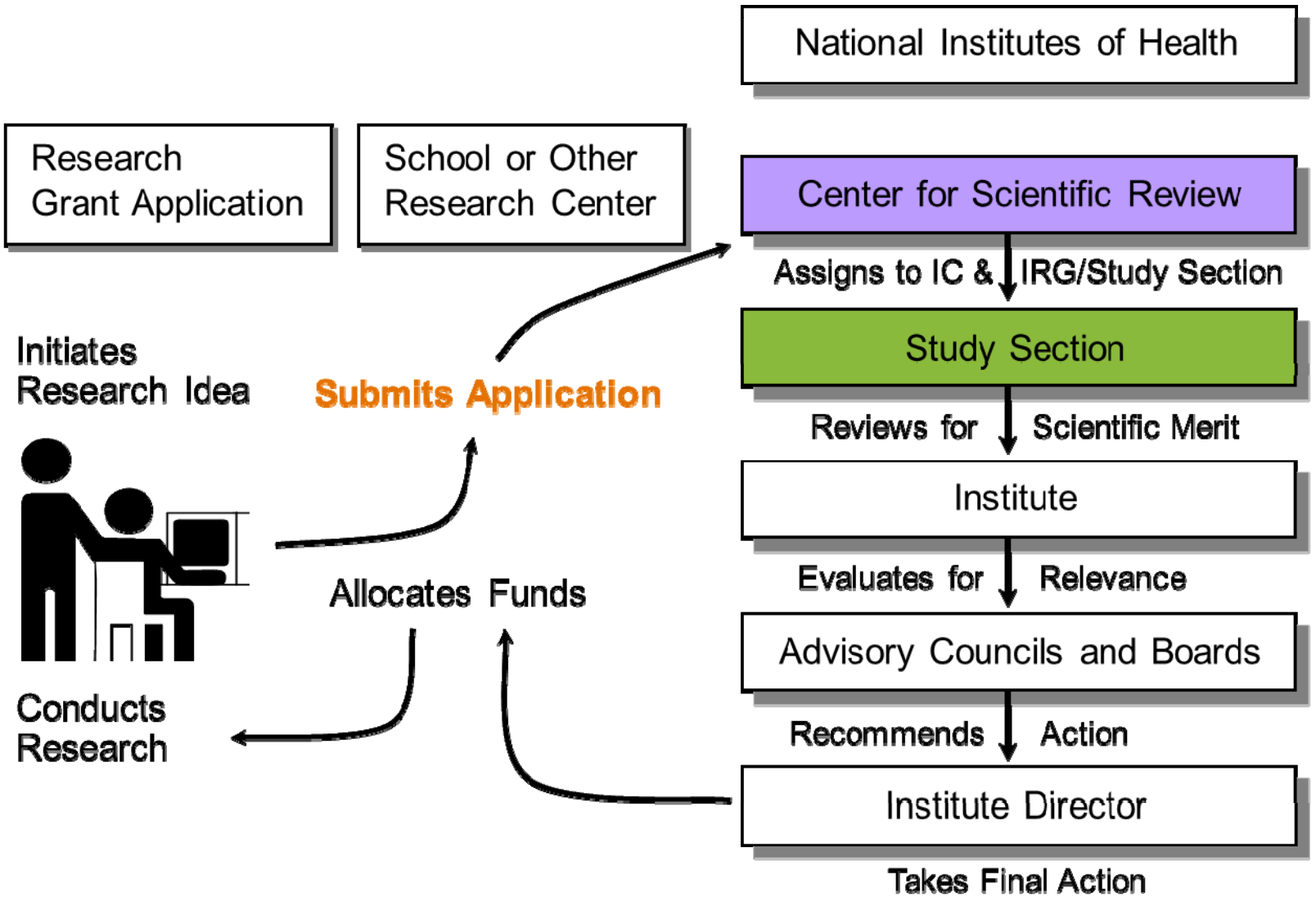
24 NIH Institutes and Centers Fund Grants



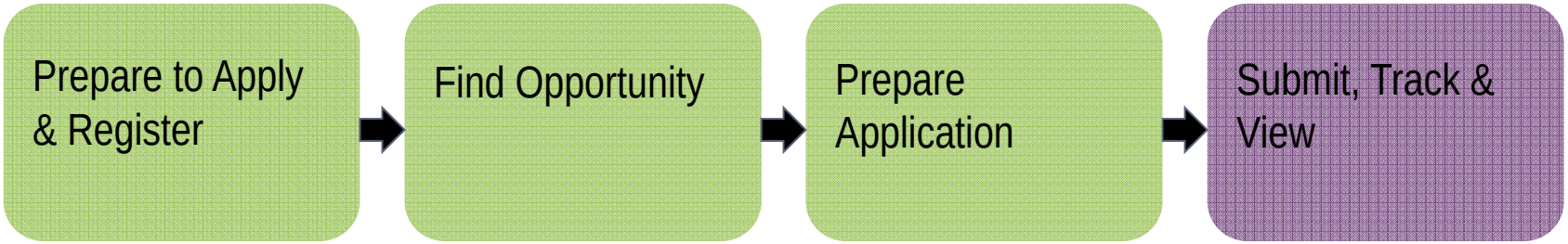
Separation of Levels of Review



Review Process for a Research Grant



Electronic Application Process (Overview)



- **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**

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

Your New Application Must Be Written as New

Your new (A0) application should not contain information that might bias the review or provide a competitive advantage:

You Cannot Refer to a Previous Review

- No mention of previous score
- No mention of previous reviewer comments
- No mention of how the A0 is responsive to previous review
- No marks in text to indicate changes

You Cannot Submit Elements of a Renewal

- No Progress Report
- No Progress Report Publication List

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

CSR Mission

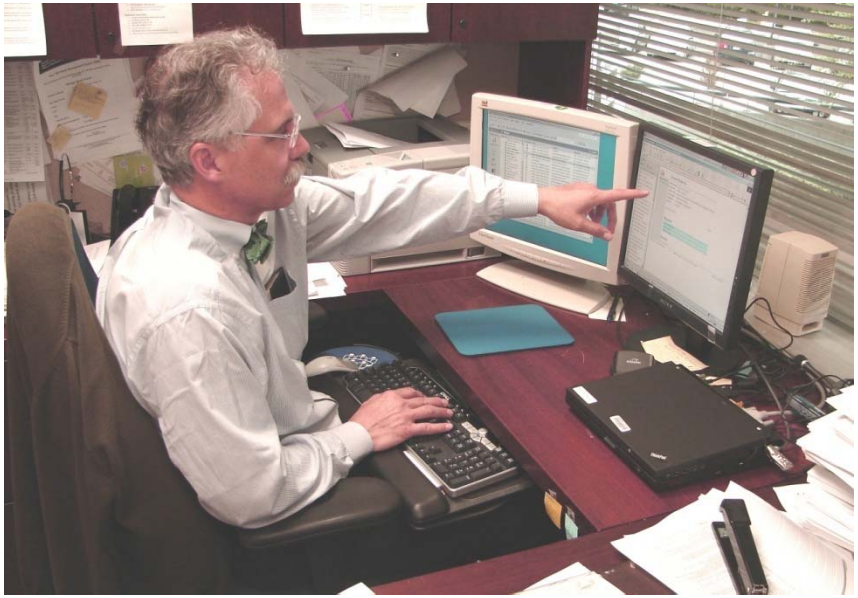
To see that NIH grant applications receive fair, independent, expert, and timely reviews – free from inappropriate influences – so NIH can fund the most promising research.

CSR Peer Review – Fiscal Year 2014

- 86,000 applications received
- 16,000 reviewers
- 237 Scientific Review Officers
- 1,500 review meetings

What does the Division of Receipt and Referral (DRR) do?

- Determines if application is
  - on time
  - formatted correctly
  - complete
- Makes Institute Assignment for funding consideration
- Makes Study Section Assignment for review

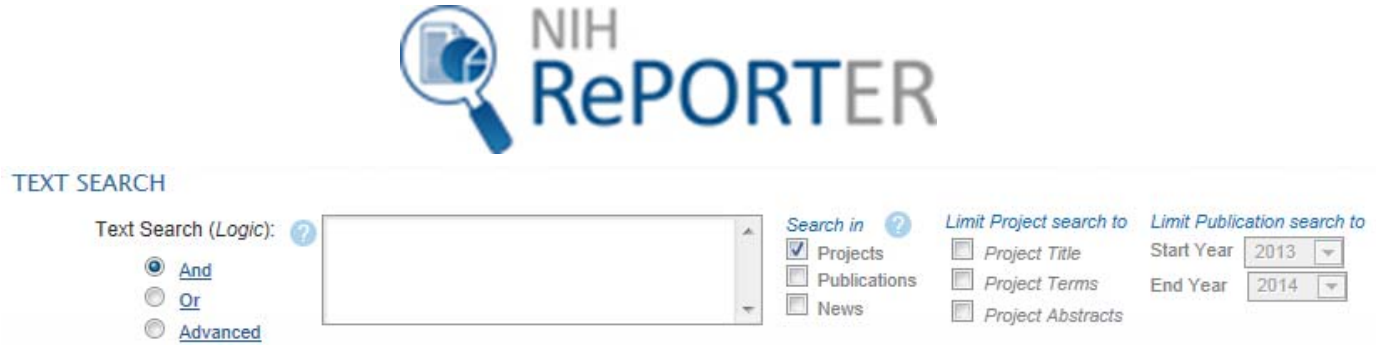


Applications Are Assigned to:

- **Institutes or Centers based on—**
  - Overall mission and guidelines of the Institute or Center
  - Specific programmatic mandates and interests of the Institute or Center
  - Dual assignments are made where applications are appropriate for more than one Institute or Center.

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

Help Your Application Get to the Right Institute

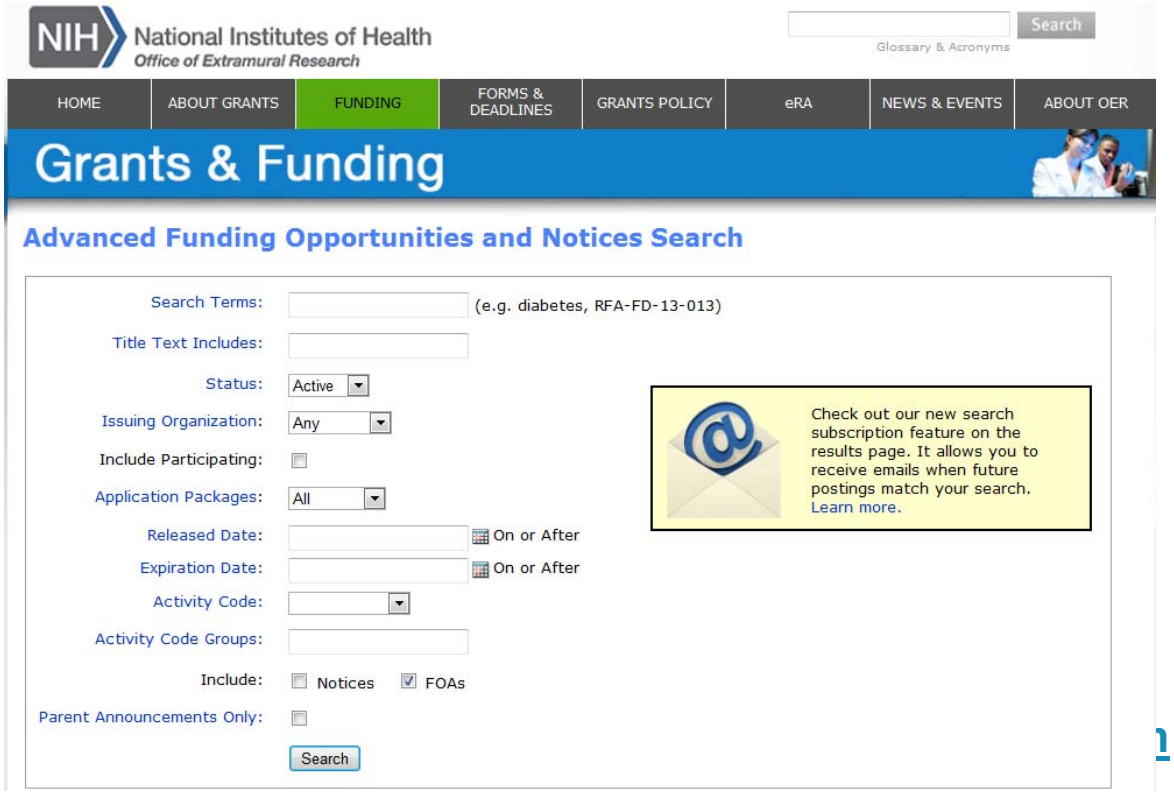


Match your application to NIH:

- Projects: Related research on the same scientific topic
- FOAs: Funding Opportunity Announcements for the topic area
- Institutes: Programs that are funding research in this topic area

http://ProjectRePORTER.NIH.gov

Find a Funding Opportunity (FOA)



Help Your Application Get to the Right Study Section

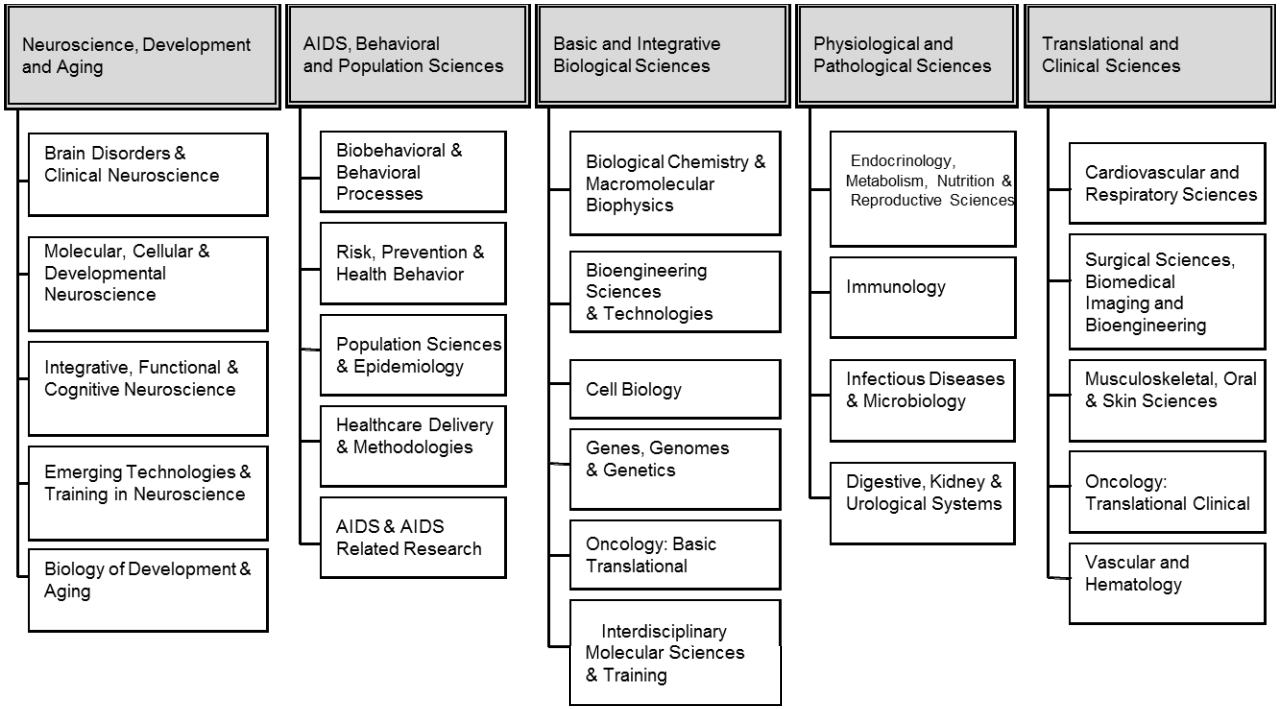
Find a Study Section

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

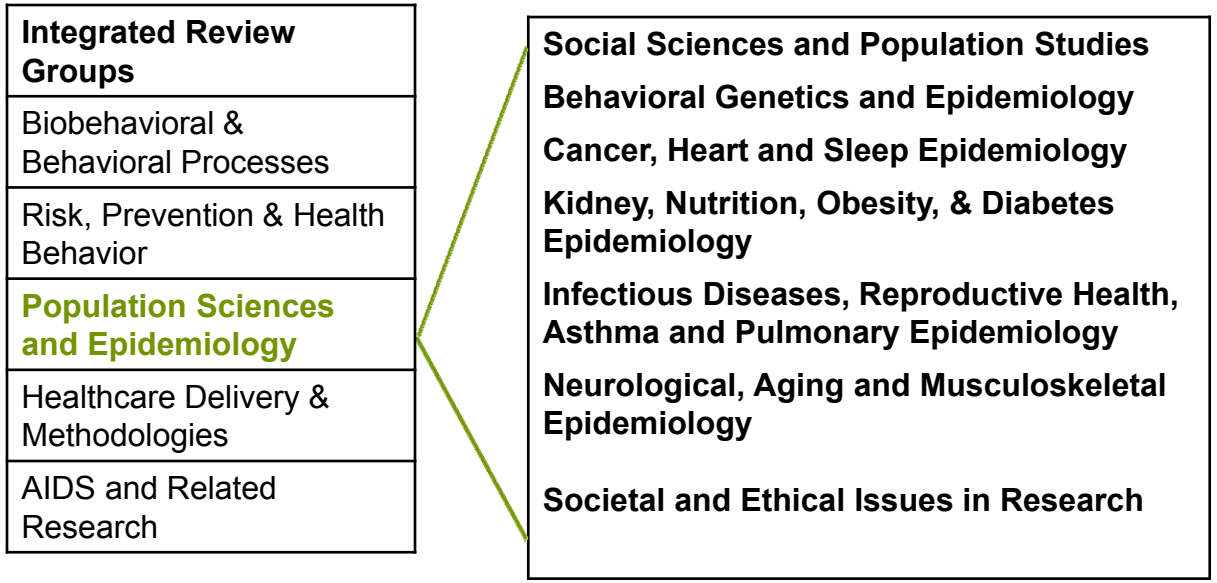
Enter Search Keywords | Go

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

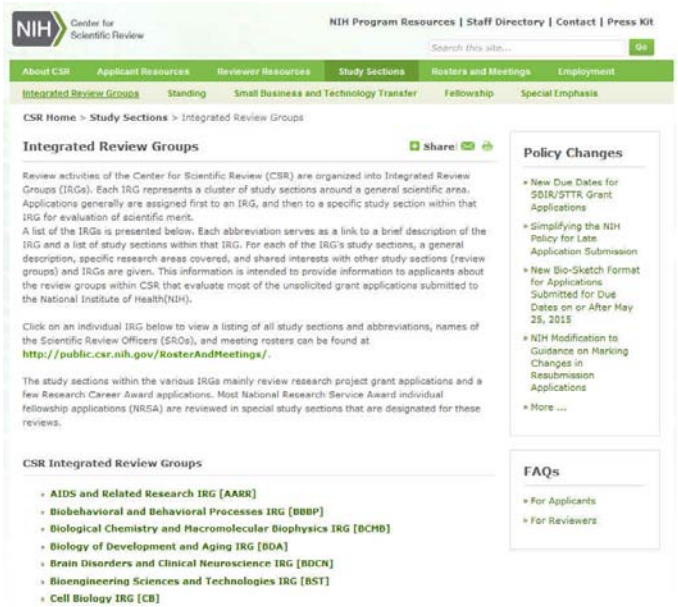
Divisions and Integrated Review Groups (IRGs)



Division of AIDS, Behavioral and Population Sciences

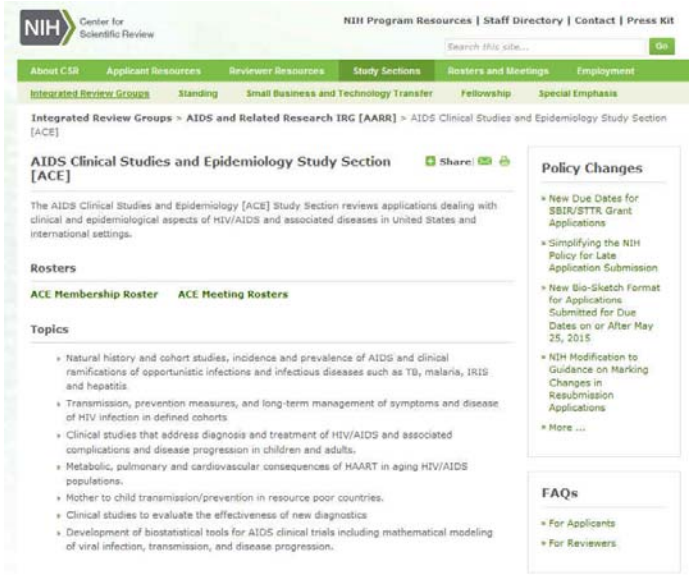


Help Your Application Get to the Right Study Section



Integrated Review Group

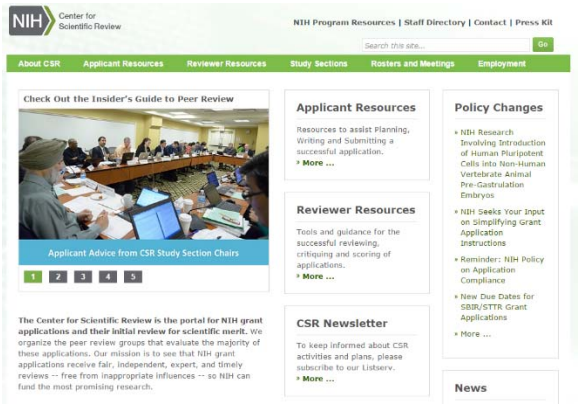
Help Your Application Get to the Right Study Section



Study Section

CSR Web Site

- About CSR
- Applicant Resources
- Study Sections
- Rosters and Meetings



http://www.csr.nih.gov

Help Get Your Application to the Right Institute and Study Section

Submit a Cover Letter!

Cover Letter

The cover letter should be used for a number of important purposes:

- Suggest Institute/Center assignment
- Suggest review group assignment
- Identify individuals in potential conflict and explain why
- Identify areas of expertise needed to evaluate the application
- Discuss any special situations

It is NOT appropriate to use the cover letter to suggest specific reviewers.

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

Suggested Cover Letter Format

- Present one request per line
- Separate positive and negative requests
- Separate IC and review requests
- Include name of IC and SRG followed by dash and acronym; do not use parentheses
- Provide explanation in separate paragraph

Sample Cover Letter

Please assign this Phase I SBIR “Drugs for Retinoblastoma Treatment” (RFA-CS-00-000) to the following:

Institutes/Centers

National Cancer Institute

National Eye Institute

Scientific Review Group

Cancer Drug Development & Therapeutics

Please do not assign this application to the following:

Scientific Review Group

Biological Chemistry, Biophysics, and Drug Discovery

This study focuses on a new in vitro model for testing drugs for treatment of retinoblastoma, not the synthesis of new chemotherapeutic agents.

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)

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
  - Dual assignments are made where applications are appropriate for more than one Institute or Center.

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

Your Application Could Be Reviewed Electronically

Electronic reviews are used to facilitate reviewer participation

Electronic Review Platforms

- Telephone Assisted Meetings
- Internet Assisted Meetings
- Video Assisted Meetings

CSR Study Sections: The Meeting

- Each CSR standing Study Section has ~12-22 regular members plus temporary reviewers from the scientific community
- About 70 applications are usually reviewed by each study section in 1-2 day meetings

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

How Reviewers Are Selected for Study Section Service

- Demonstrated scientific expertise/research support
- Doctoral degree or equivalent
- Mature judgment
- Work effectively in a group context
- Breadth of perspective
- Impartiality
- Representation of women and minority scientists
- Geographic distribution

Where Do We Find Reviewers?

- CSR electronic resources
- Successful applicants
- Recommendations from reviewers and NIH staff
- NIH RePORTER (http://projectreporter.nih.gov/reporter.cfm)
- Internet
- Scientific conferences

The SRO Assigns at Least Three Reviewers to an Application

Reviewer Conflicts of Interest (COI)

What Constitutes a Reviewer COI?

- Institutional
- Family member/close friend
- Collaborator
- Longstanding scientific disagreement
- Personal bias
- Appearance of conflict

http://grants.nih.gov/grants/peer/peer_coi.htm

Confidentiality

- Review materials and proceedings of review meetings represent privileged information for reviewers and NIH staff.
- At the end of each meeting, reviewers must destroy or return all review-related material.
- Reviewers should not discuss review proceedings with anyone except the SRO.
- Questions concerning review proceedings should be referred to the SRO.
- Applicants should never communicate directly with any members of the study section about an application.

The Study Section Meeting

- Closed Meeting
- Orientation
  - Conflict of Interest
  - Confidentiality
  - Developments of interest to the study section
  - Changes in policy or procedure
  - Roles of the persons present
    - Chair and other Reviewers
    - Program Officers (Observers)
    - SRO
- Application by Application review

Your Scientific Review Officer

During and After the Review Meeting

- Manages the meeting
- Prepares summary statements
- Provides information to NIH Institutes and Centers

Role of Study Section Chair

- Partners with their Scientific Review Officer to conduct the meeting
- Guides and summarizes study section discussion
- Ensures all study section member opinions are given careful consideration
- Manages scientific discussions at the meeting, e.g., timeliness and thoroughness

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

New and Early Stage Investigators

- New Investigator (NI)
  – PD/PI who has not yet competed successfully for an R01 or other substantial NIH research grant

- Early Stage Investigator (ESI)
  – PD/PI who qualifies as a New Investigator AND is within 10 years of completing the terminal research degree or is within 10 years of completing medical residency

http://grants.nih.gov/grants/new_investigators/

Review of Each Application

- Reviewers with conflicts leave room
- Assigned reviewers state preliminary scores
- Discussion of scientific and technical merit
  - Based on the 5 review criteria
  - Assigned reviewers first then open discussion to whole committee
- Discussion of Protection of Human Subjects and Inclusion criteria
- Assigned reviewers state final score – range of scores is set
- Every eligible member scores each application
- Budget and Administrative concerns
- Ideal time for each application - 15 to 20 minutes

Additional Criteria Contribute to Overall Impact Scores

- Protections for human subjects
- Inclusions of women, minorities, and children
- Appropriate use of vertebrate animals
- Management of biohazards

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

Vertebrate Animal Welfare

Important Considerations

- Proposed use of the animals, and species, strains, ages, sex, and numbers to be used
- Justifications for the use of animals and for the appropriateness of the species and numbers proposed
- Adequacy of veterinary care
- Procedures for limiting discomfort, distress, pain and injury
- Euthanasia in accord with American Veterinary Medical Association guidelines

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.

Scoring

- Score applications on five core criteria using a scale of 1-9
- Preliminary overall impact/priority score using 1-9 scale
- Discussed applications receive an overall score from each eligible (i.e., without conflicts of interest) panel member, and these scores will be averaged to one decimal place, and multiplied by 10. The 81 possible priority scores will thus range from 10-90.
- All applications will receive scores:

  Not discussed applications will receive initial criterion scores from the three assigned reviewers.

Review Criteria

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

- Core Review Criteria
  - Significance
  - Investigator(s)
  - Innovation
  - Approach
  - Environment

Review criteria each 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 Philosophy

Overall Impact:
The likelihood for a project to exert a sustained, powerful influence on research field(s) involved

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment) and other score influences (e.g. human subjects)

e.g. Applications are addressing a problem of high importance/interest in the field. May have some or no technical weaknesses.

e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.

e.g. Applications may be addressing a problem of moderate importance in the field, with some or no technical weaknesses

e.g. Applications may be addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.

e.g. Applications may be addressing a problem of low or no importance in the field, with some or no technical weaknesses.

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.

Priority Scores

- For each study section, applications in the upper half may be scored from 1-9, with 1 the best score.
- Individual scores are averaged and multiplied by 10 to give the final priority score

After Your Review

Your SRO

- Prepares summary statements
- Provides information to NIH Institutes and Centers

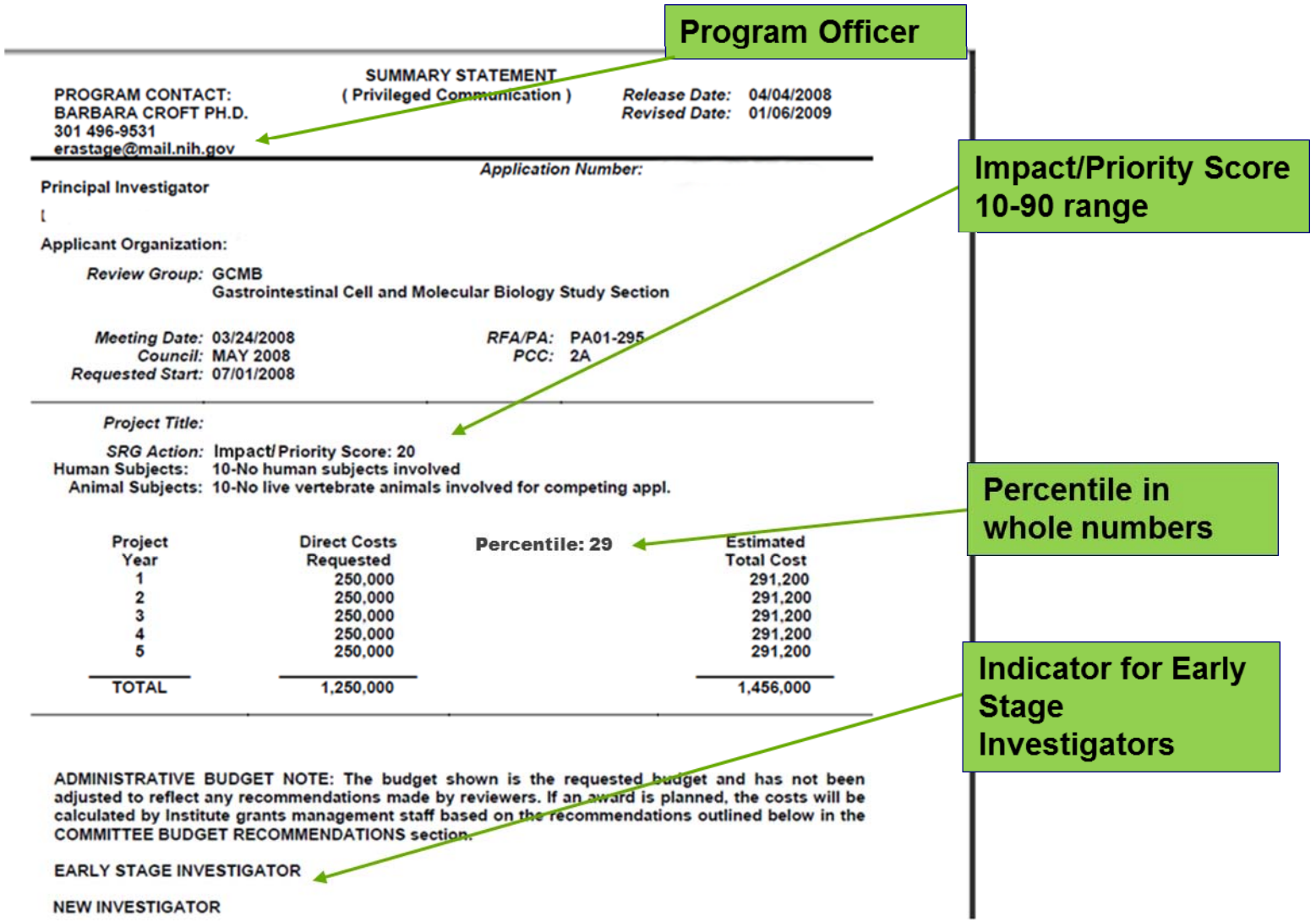
Your Summary Statement

- 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



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.

Percentile: 29

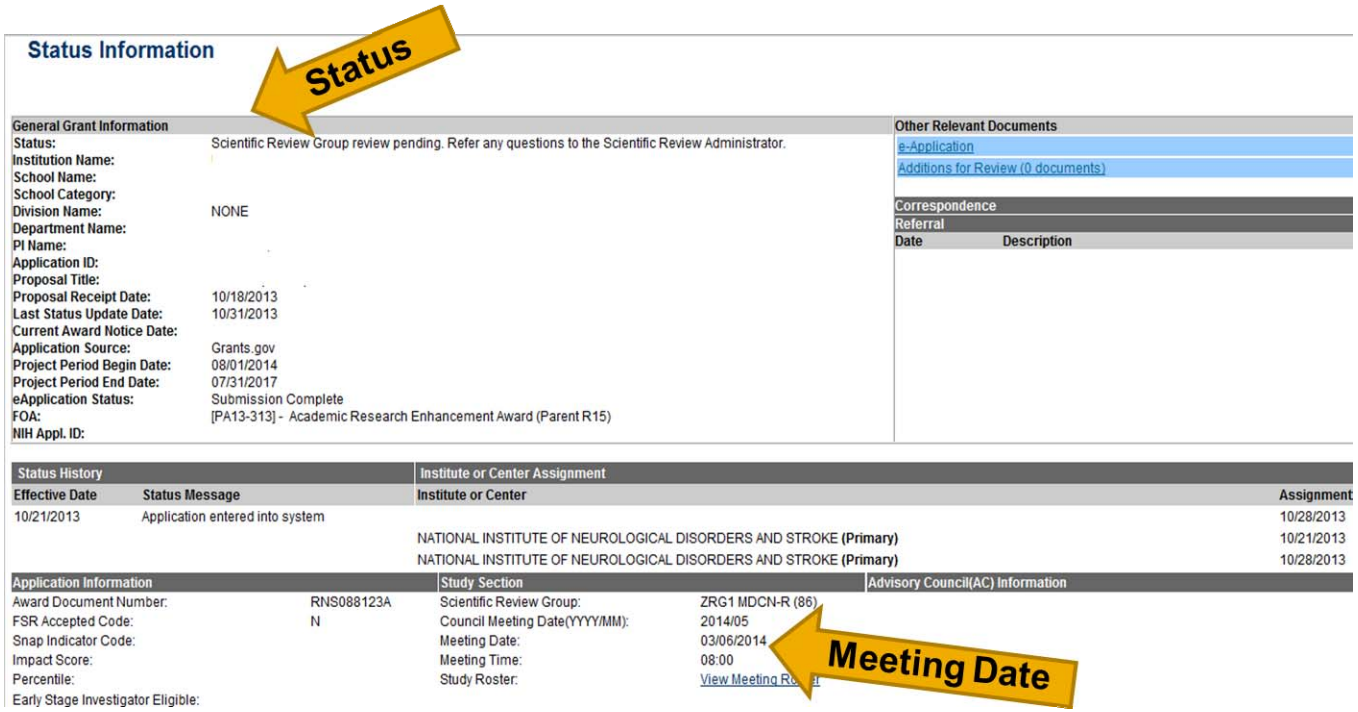
Project Year	Direct Costs Requested	Estimated Total Cost
1	250,000	291,200
2	250,000	291,200
3	250,000	291,200
4	250,000	291,200
5	250,000	291,200
TOTAL	1,250,000	1,456,000

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

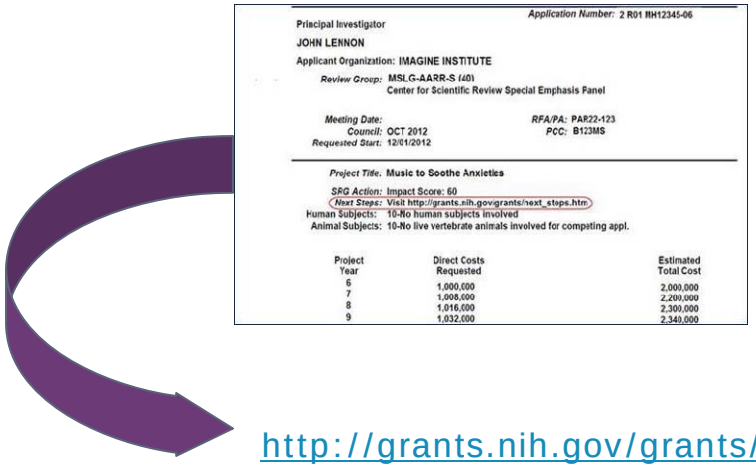
NEW INVESTIGATOR

Check the Status of Your Application in NIH Commons



Your Application Was Reviewed
What Do You Do Next?

Visit NIH's Next Steps Website



Application Number: 2 R01 MH12345-06

Principal Investigator
JOHN LENNON

Applicant Organization: IMAGINE INSTITUTE

Review Group: MSLG-AARR-S (40)
Center for Scientific Review Special Emphasis Panel

Meeting Date:
Council: OCT 2012
Requested Start: 12/01/2012

RFA/PA: PAR22-123
PCC: B123MS

Project Title. Music to Soothe Anxieties

SRG Action: Impact Score: 60
Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm
Human Subjects: 10-No human subjects involved
Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Project Year	Direct Costs Requested	Estimated Total Cost
6	1,000,000	2,000,000
7	1,008,000	2,200,000
8	1,016,000	2,300,000
9	1,032,000	2,340,000

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

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

U.S. Department of Health & Human Services

NIH Center for Scientific Review

Jumpstart Your Career:
CSR Early Career Reviewer Program

Early Career Reviewer Program Goals

- Train and educate qualified scientists to become critical and well-trained reviewers
- Expose investigators to the peer review experience to help make them more competitive as applicants
- Enrich the existing pool of NIH reviewers

Qualifications for the Early Career Reviewer Program

- Demonstrated training and experience in the scientific areas under review as evidenced by:
  - A faculty appointment or equivalent
  - An active independent program of research
  - At least 2 senior authored research publications in peer reviewed journals in the past 2 years
- Has not previously served on a CSR Study Section
- Has not been PI on an R01 award

ECR Service

- Attend study section meeting
- Assigned 2-4 applications as 3rd reviewer
- Write full critiques for assigned application
- Participate in one study section meeting

View the Video

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

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

How to Apply for the Early Career Reviewer Program

- Instructions are at www.csr.nih.gov/ECR
- If eligible, your name will be placed into our ECR database
- You will be invited to serve as an ECR when your expertise is needed for particular applications

CSR and NIH Information Sources

NIH Peer Review Information on the Web

National Institutes of Health: http://www.nih.gov

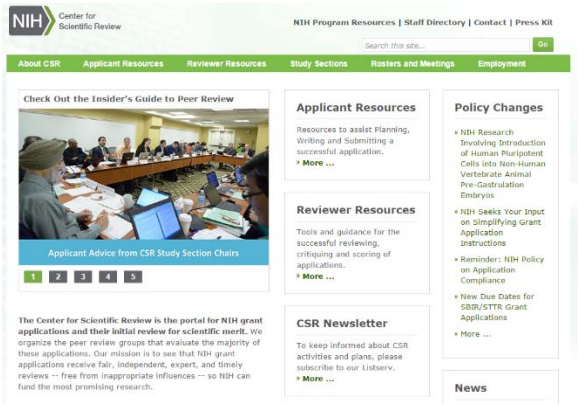
- **Office of Extramural Research**
  http://grants.nih.gov/grants/oer.htm
- **Grants Policy**
  http://grants.nih.gov/grants/policy/policy.htm
- **Electronic Submission**
  http://grants.nih.gov/grants/electronicReceipt/index.htm

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

CSR Web Site

- About CSR
- Applicant Resources
- Study Sections
- Rosters and Meetings

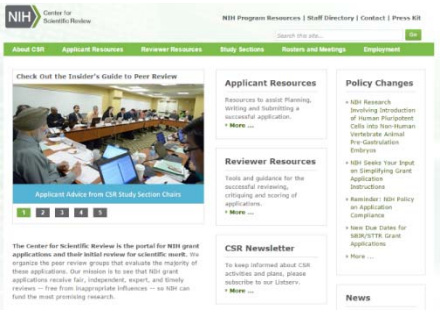


http://www.csr.nih.gov

Key NIH Review and Grants Web Sites

NIH Center for Scientific Review

http://www.csr.nih.gov



NIH Office of Extramural Research

http://grants.nih.gov/

The NIH Web Site

http://www.nih.gov

Helpful Handouts

Insider's Guide to Peer Review

Insider's Guide to Peer Review for Applicants

NIH Center for Scientific Review

To help new and established applicants submit better applications, CSR asked current and recent study section chairs to share their personal insights on producing a highly competitive NIH grant application. They responded with great enthusiasm.

Don't jump too fast into writing your application: Since the most critical parts are the summary and specific aims sections, write a one-page summary page with specific aims first and share it with someone who is experienced, has their own funding or—ideally—someone who has served on a study section. If you can't wow them, start again and use the time you saved to come up with some fresh ideas.

Propose something significant: It is a real turn-off to read an application that is basically a re-hash of a previous project with a new issue. The same goes for "me too" research. Identify an area of current controversy and importance within your field. Make it something that would interest more people than you and your coworkers. Will it be important to clinicians or other investigators? Are you dealing with key questions or controversies in the field?

Good ideas don't always sell themselves: Tell me why it's important up front in the background section, and I'll be ready to roll. Tell me what's known and what isn't known and how, after you complete your studies, you'll move the field forward or answer important questions. A lot of people really are unaware of how absolutely important it is to tell the reviewer from the beginning why it's worth doing. If you're seeking an incremental advance over what's known, it's essential to justify it.

What Happens to Your Grant Application

What Happens to Your Grant Application
A Primer for New Applicants

The Center for Scientific Review (CSR) receives all NIH and some other Public Health Service grant applications. Most investigator-initiated applications for NIH funds are referred to CSR review groups.

Your application is assigned to a review group and an NIH Institute or Center

One or more CSR Referral Officers examine your application and determine the most appropriate Integrated Review Group (IRG) to assess its scientific and technical merit. Your application is then assigned to one of the IRG's study sections. A study section typically includes 20 or more scientists from the community of productive researchers. Your application also will be assigned to the NIH Institute or Center (IC) best suited to fund your application should it have sufficient merit. (More than one IC may be assigned if appropriate.)

Referral Officers follow established guidelines that define the review boundaries of each study section. These boundaries frequently overlap, and more than one study section may have the expertise to review your application. You may request in a cover note with your application that it be assigned to a particular study section or IC. The CSR referral office seriously considers such requests.

The combined expertise of the scientists in a study section is intended to span the breadth and diversity of the science it covers. CSR may recruit temporary reviewers or secure mail reviews from outside consultants.

One of CSR's Referral Officers who helps assign applications to the right review groups and ICs. CSR expands its scan use text-fingerprinting software to help speed referrals.

Checking the status of your application

As soon as your application is received and assigned to a study section, notices are posted to your online NIH Commons account. Information on the Commons and how to register is available at https://commons.era.nih.gov/commons. You may question either your study section or IC assignment by contacting the Scientific Review Officer (SRO) (previously called Scientific Review Administrator [SRA]) named in your notification or the CSR referral office (301-435-0715). It usually takes weeks to refer the thousands of applications submitted each round. If a notice is not posted in your Commons account within 2 weeks of the submission date, you should contact the referral office.

Reviewers are identified

Your SRO will analyze the content of your application, check for completeness, and decide which reviewers can best evaluate it. Reviewers receive a copy of your application approximately 4 weeks before their meeting. Each application is assigned to three reviewers, and at least two of them provide written critiques. These assigned reviewers lead the discussions at the meeting.

Because of the multi-month period between submission and review, applicants often wish to submit additional materials. Before you do, you should contact your SRO to see if this is possible and what kinds of limitations apply.

Some of about 18,000 scientists who review NIH grant applications at CSR.

NIH Grant Application Useful Web Links

NIH Grant Application
Submission and Review

Useful Web Links

Center for Scientific Review ** http://www.csr.nih.gov ** 301-435-1115

- NIH Peer Review Revealed Video
  http://www.csr.nih.gov/video/video.asp
- CSR's Early Career Reviewer Program
  http://www.csr.nih.gov/ECR
- The Peer Review Process
  http://www.csr.nih.gov/ApplicantResources/The-Peer-Review-Process
- Insider's Guide to Peer Review for Applicants
  http://www.csr.nih.gov/ApplicantResources/Insider/
- CSR Study Section Information – Descriptions, Rosters, Meeting Dates, etc.
  http://public.csr.nih.gov/StudySections
- More Helpful Web Links
  http://www.csr.nih.gov/links

NIH Office of Extramural Research ** http://www.grants.nih.gov

- Overview of the NIH Grants Process
  http://grants.nih.gov/grants/grants_process.htm
- NIH Guide for Grants and Contracts
  http://grants.nih.gov/grants/guide/index.html
- Writing Your Application
  http://grants.nih.gov/grants/writing_application.htm
- Extramural Training Opportunities
  http://grants.nih.gov/training/extramural.htm

The OER GrantsInfo service provides information and answers to general questions on funding opportunities and grant application forms, instructions, and policies: grantsinfo@nih.gov or phone 301-435-0714.

National Institutes of Health
http://www.nih.gov

November 2014

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

NIH Guide

For Grants and Contracts

U.S. Department of Health and Human Services

- Announces NIH Scientific Initiatives
- Provides NIH Policy and Administrative Information
- Supplies links to application forms
- Available on the NIH Web Site: http://www.nih.gov

A Window to Your Application: eRA Commons

eRA Commons is an online interface where a grant applicant can:

- Check submitted grant application for errors and warnings and view final image
- Track review assignment, view review outcomes (score, summary statements), find contact info
- Update Personal Profile to ensure Early Stage Investigator eligibility is in place
- Submit pre-award information (just in time)
- View Notice of Award and other key documents

And much more!

https://commons.era.nih.gov/commons/

NIH Encourages Applicants to Describe their Research in Terms Easily Understood by Reviewers, Scientists, Congress and the Public

Titles, statements of public health relevance & abstracts should:

- Convey value of research in plain language
- Be understandable by both scientists and the public
- Clearly relay the potential impact of the research on health

The public accesses funded NIH grant info through http://ProjectRePORTER.NIH.gov

Examples and more info: http://grants.nih.gov/grants/plain_language.htm

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NIH's Resubmission Policy

After an unsuccessful new (A0) application or an unsuccessful resubmission (A1) application, you may submit a new (A0) application with the same idea as long as your summary statement has been issued.

NIH Guide Notices

- NOT-OD-14-074
- NOT-OD-14-082

Resubmission FAQs

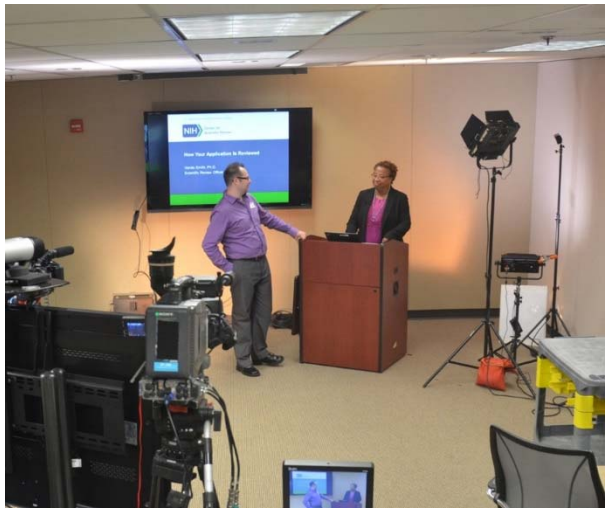
http://grants.nih.gov/grants/policy/resubmission_q&a.htm

View the Videos

- NIH Peer Review Revealed
- Jumpstart Your Research Career with CSR's Early Career Reviewer Program
- NIH Tips for Applicants
- What Happens to Your NIH Grant Application

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

Meet the Experts in NIH Peer Review Webinars



For Researchers Seeking:

- R01 Grants
- Fellowship Awards
- AREA/R15 Grants
- Small Business Grants

www.csr.nih.gov/webinar