The NIH Peer Review Process

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Health Care Delivery and Methodologies Integrated Review Group

Division of AIDS, Behavioral and Population Sciences

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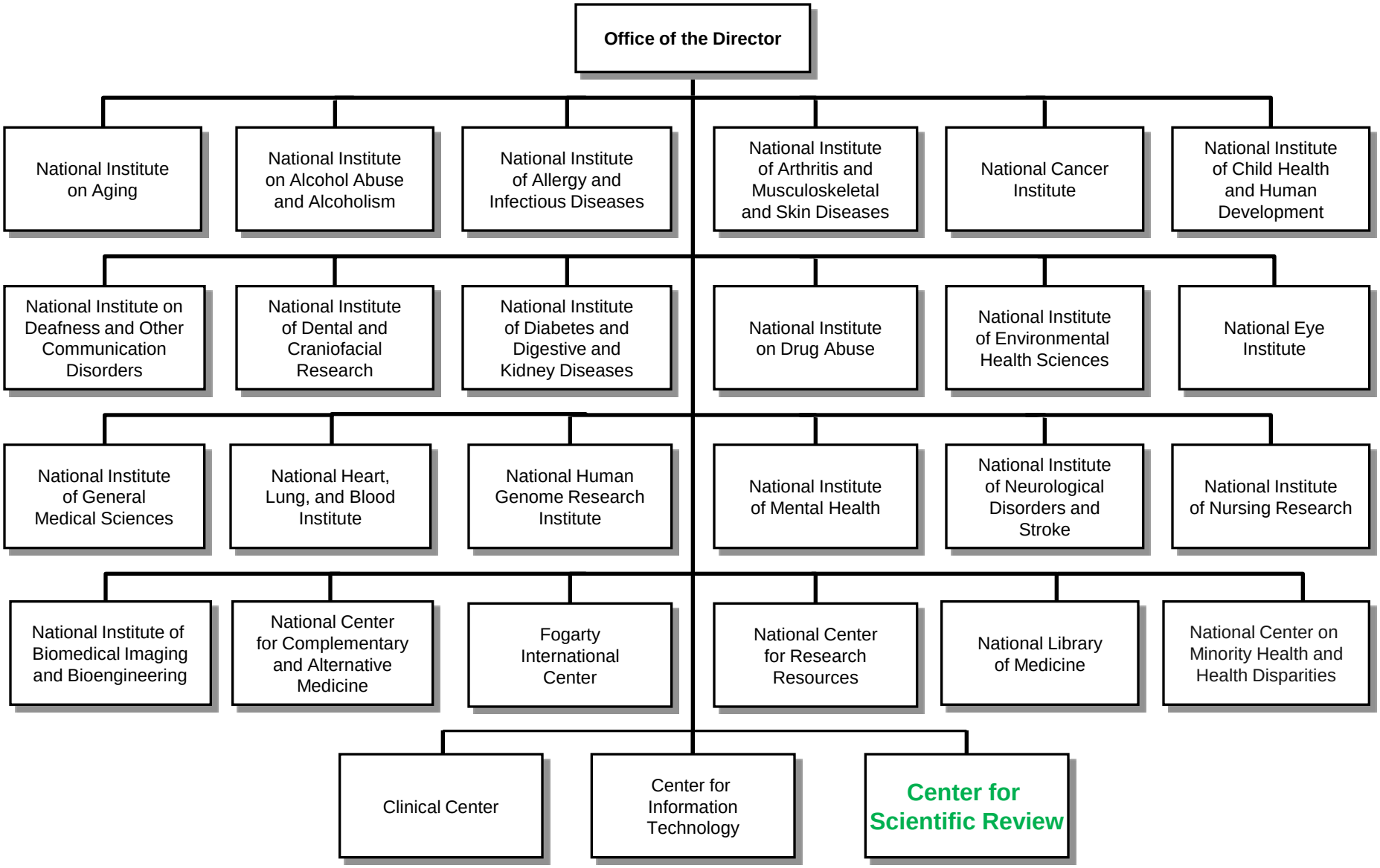
center for scientific review

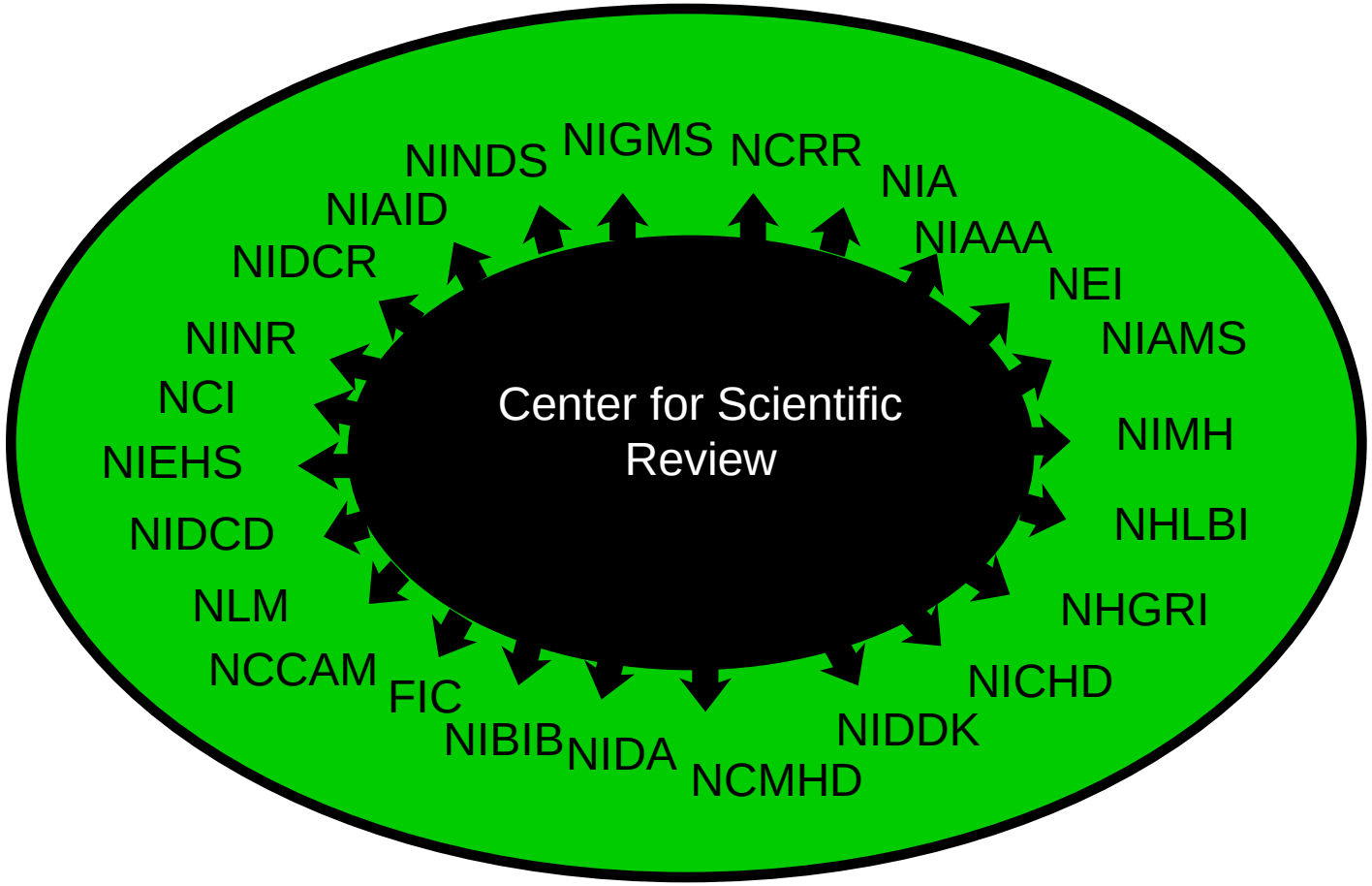
National Institutes of Health

U.S. Department of Health and Human Services

National Institutes of Health



24 NIH Institutes and Centers Fund Grants



CSR Referral

Applications Are Assigned to:

- **Scientific Review Groups for review based on:**
  - **Specific referral guidelines for each scientific review group**
- **NIH Institutes or Centers for funding based on:**
  - **Overall mission of the Institute or Center**
    - **Referral guidelines for each funding IC**
  - **Specific programmatic mandates and interests of the Institute or Center**

CSR Peer Review – Fiscal Year 2010

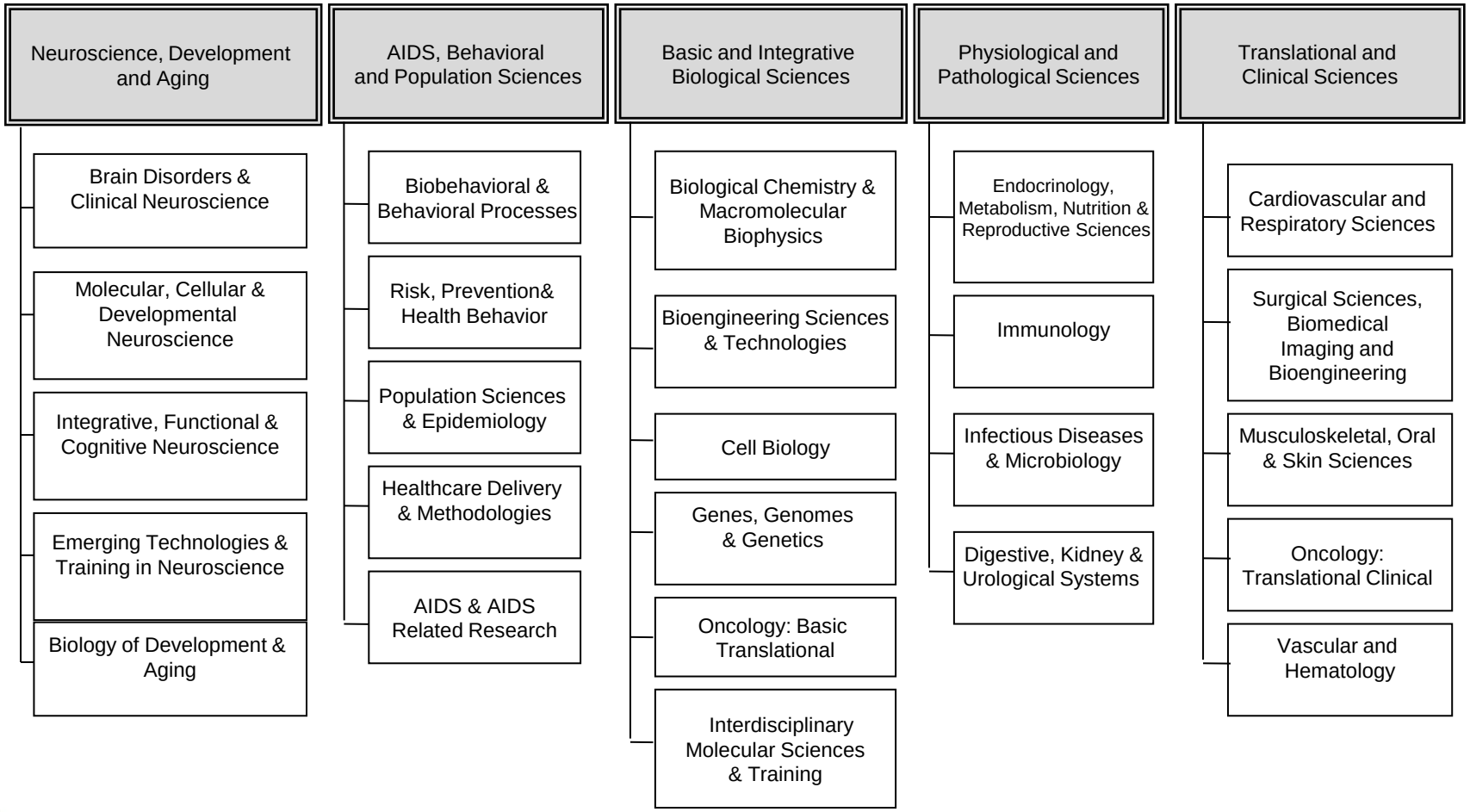
- **88,000 applications received**
- **61,000 applications reviewed**
- **18,000 reviewers**
- **240 Scientific Review Officers**
- **1,600 review meetings**

Where are Applications Reviewed?

- **CSR**
  - Research Projects
  - Academic Research Enhancement Awards
  - SBIR & STTR
  - Shared Instrumentation
  - Career Awards
  - Small Grants
  - Fellowships
  - RFAs
- **Institutes/Centers**
  - Contracts
  - Program Projects (most)
  - Institutional Training Grants
  - Conference Grants
  - Centers
  - Career Awards
  - Small Grants
  - Fellowships
  - RFAs

CSR

Divisions and Integrated Review Groups (IRGs)



Division of AIDS, Behavioral and Population Sciences

- Biobehavioral & Behavioral Processes
- Risk, Prevention & Health Behavior
- **Population Sciences and Epidemiology**
  - Social Sciences and Population Studies
  - Behavioral Genetics and Epidemiology
  - Cardiovascular and Sleep Epidemiology
  - Epidemiology of Cancer
  - Kidney, Nutrition, Obesity, & Diabetes Epidemiology
  - Infectious Diseases, Reproductive Health, Asthma and Pulmonary Epidemiology
  - Neurological, Aging and Musculoskeletal Epi
- Healthcare Delivery and Methodologies
- AIDS and Related Research

Division of AIDS, Behavioral and Population Sciences

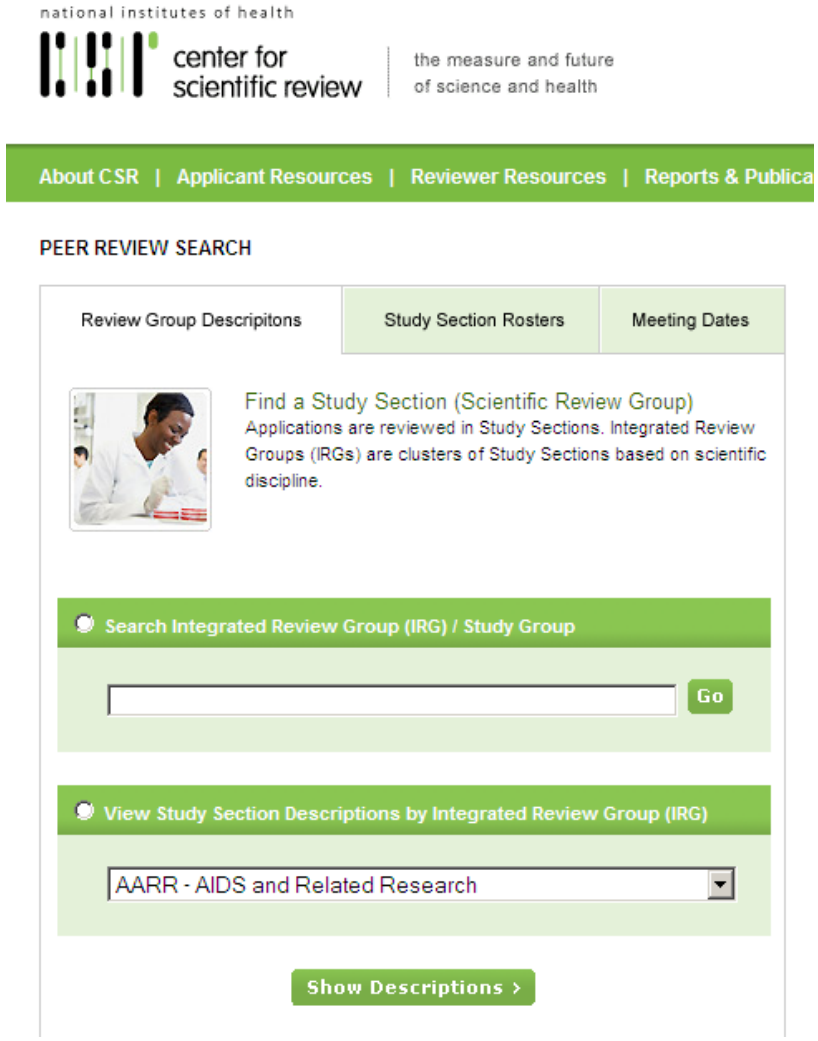
- Biobehavioral & Behavioral Processes
- Risk, Prevention & Health Behavior
- Population Sciences and Epidemiology
- **Healthcare Delivery & Methodologies**
  - Biostatistical Methods and Research Design
  - Biomedical Computing and Health Informatics
  - Community-Level Health Promotion
  - Community Influences on Health Behavior
  - Dissemination and Implementation Research in Health
  - Health Disparities and Equity Promotion
  - Health Services Organization and Delivery
  - Nursing and Related Clinical Sciences
  - Societal and Ethical Issues in Research
- AIDS & Related Research

Help Get Your Application to the Right Study Section

- **Review CSR Integrated Review Group and Scientific Review Group (Study Section) guidelines to identify a home for your application.**

- **Submit a Cover Letter!**

Help Your Application Get to the Right Study Section



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

Help Your Application Get to the Right Study Section

For a listing of the Scientific Review Officer and membership roster for each study section, click on the study section roster under the study section name within an IRG listed below or go to the study section index (study sections listed alphabetically) and click on the specified roster next to the name of the study section.

Cardiovascular and Respiratory Sciences IRG [CVRS]

Printer Friendly (Complete IRG)

The Cardiovascular and Respiratory Sciences [CVRS] IRG will consider research applications that employ basic investigations, translational approaches and patient-oriented studies to focus on the development, physiology, and pathophysiology of the cardiac and pulmonary systems. Cardiac study sections are organized around themes of cardiac development, muscle contraction including cardiac hypertrophy and failure, cardiovascular electrophysiology and arrhythmias, myocardial ischemia and metabolism and include a study section devoted to clinical investigation. Respiratory study sections focus on inflammation and immune dysfunctions in the lung, lung injury, repair and remodeling, and the integrative biology and control mechanisms of the lung and its related organs and tissues. Investigators may employ a range of approaches that include genetics, genomics and proteomics, molecular, cell, and computational biology, biochemistry, biophysics and bioengineering, imaging, analyses of model organisms, and human studies.

The following study sections are included within the CVRS IRG:

Integrated Review Group

Help Your Application Get to the Right Study Section

Clinical and Integrative Cardiovascular Sciences Study Section [CICS]

[CICS Membership Roster] [CICS Meeting Rosters]

The Clinical and Integrative Cardiovascular Sciences [CICS] Study Section considers patient oriented research involving the cardiovascular system and related regulatory organ systems. Patient oriented research is defined as studies involving investigation of the cardiovascular system of humans, including autonomic physiology and exercise cardiovascular studies and extending to include surgery and pediatrics. Clinical trials that are secondary prevention focusing on outcomes may be assigned to CICS. Applications for randomized multi-center clinical trials are not appropriate for CICS. Specific areas covered by CICS:

- Human clinical studies (and appropriate translational animal studies): including pediatric populations, mechanisms and consequences of disease: Investigations may include: coronary physiology and pharmacology, cardiac electrophysiology, regional circulations, hemodynamic studies, cardiac mechanics, and genetic considerations in cardiovascular studies. Disease states can include: cardiac or vascular ischemia, hypertension, diabetes, thyroid disease, atherosclerosis, general inflammation, or hypercholesterolemia.
- Modulation of cardiac/cardiovascular responses and adaptations: influence of acute and chronic exercise on metabolic function and cardiac, vascular smooth muscle, and vascular endothelial function(s). Pregnancy and aging may be considered modulatory influences.
- Neural control of the cardiovascular system: includes healthy and diseased populations and central and peripheral autonomic physiology, pharmacology, and receptor mechanisms.
- Clinical, population, or translational studies of the responses of the cardiovascular system to trauma or surgery: arrhythmias associated with cardiac surgery or cardiopulmonary bypass, cardiac sudden death, resuscitation, stenting, pacemakers; cardiovascular injury and repair, and myocardial ischemia/reperfusion injury.
- Environmental stresses and modifying conditions/stimuli: smoking, altitude, microgravity, heat, cold, bed rest/deconditioning, and environmental pollution in patients.

Study sections with most closely related areas of similar science listed in rank order are:

Cardiac Contractility, Hypertrophy, and Failure [CCHF]
Hypertension and Microcirculation Study Section [HM]
Atherosclerosis and Inflammation of the Cardiovascular System [AICS]
Cardiovascular and Sleep Epidemiology [CASE]
Bioengineering, Technology, and Surgical Sciences [BTSS]

Study Section

Cover Letter

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

- Suggest Institute/Center assignment
- Suggest review 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.

Sample Cover Letter

Please assign this application "Immunology of Kidney Transplant Rejection" to the following:

Institutes/Centers

National Institute of Diabetes, Digestive and Kidney Diseases (primary)

National Institute of Allergy and Infectious Diseases (dual)

Scientific Review Group

Digestive, Kidney, and Urological Systems

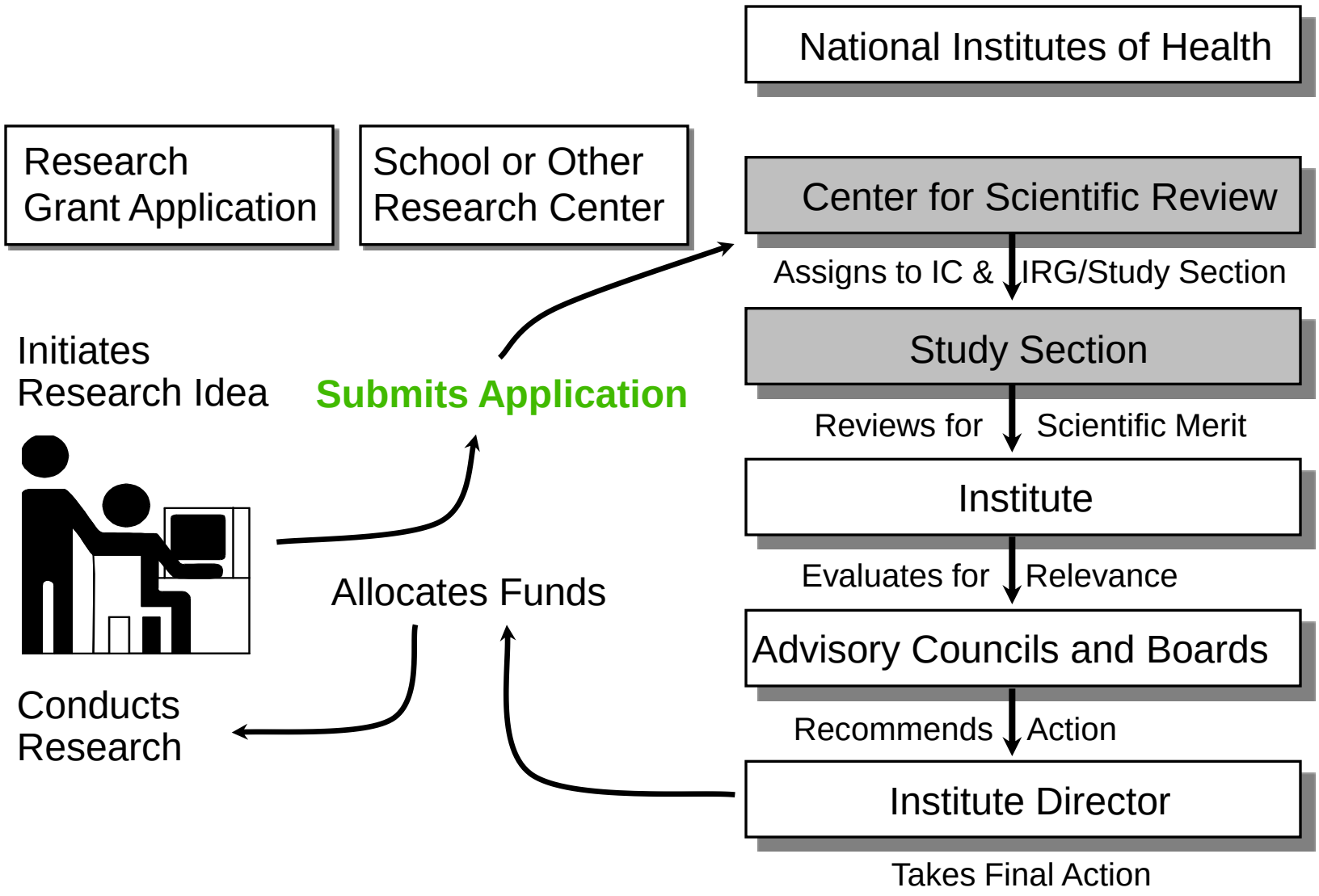
Please do not assign this application to the following:

Scientific Review Group

Immunology IRG

This study focuses on improving outcomes specifically for kidney transplant, <u>not</u> general immunological aspects.

Review Process for a Research Grant



Core Review Criteria for R01 Applications

Significance. ***Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?***

Investigator(s). ***Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?***

Core Review Criteria for R01 Applications

Innovation. ***Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?***

Approach. ***Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?***

Environment. ***Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?***

Additional Criteria

Resubmission Applications. ***(formerly called an amended application), the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.***

Renewal Applications. ***(formerly called a competing continuation application), the committee will consider the progress made in the last funding period.***

Revision Applications*. (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the*

Scientific Review Process

Dual Review System for Grant Applications

First Level of Review

CSR or Institute Review

Scientific Review Group

(Study Section)

Second Level of Review

NIH Institute/Center Council

CSR Study Sections

- Each CSR standing study section has 12-28 regular members who are primarily from academia
- Ad Hoc members
- CSR standing study sections convene face-to-face meetings
- As many as 60-100 applications are reviewed by each study section

Criteria for Selection of Peer Reviewers

- Active and productive researchers
- Demonstrated scientific expertise
- Mature and impartial judgment
- Work effectively in a group context
- Breadth of perspective
- Interest in serving
- Diversity of gender, ethnicity and geography

Where Do We Find Reviewers?

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

Pre-Meeting Activities - Reviewers

- Reviewers receive applications and assignments 6-8 weeks prior to meeting
  - Identify conflicts of interest
  - Generally assigned between 8-12 applications
  - Write critiques prior to the meeting
- Post preliminary scores and critiques on secure meeting website
- Read written critiques of other reviewers a few days before the meeting

What Happens at 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

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

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_____ _____

_____ _____

_____ _____

Confidentiality

- Review materials and proceedings of review meetings represent privileged information to be used only by reviewers and NIH staff.
- At the conclusion of each meeting, reviewers will be asked to 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.

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 member scores each application
- Budget and Administrative concerns
- Ideal time for each application - 15 to 20 minutes

View the Videos

- **NIH Peer Review Revealed**
- **NIH Tips for Applicants**

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

Separation of Funding and Review

Program Staff:

-Identify and promote research priorities

-Recommend projects for funding (based on score, budget, priorities)

-Manage portfolio of projects

-Work with applicants up to review and after review

Review Staff:

-Manage study section meetings to evaluate scientific and technical merit

-Provide a fair, thorough and competent review for each application

-Work with applicants before review

Enhancing Peer Review Background

Year-long Deliberative Effort Gathering Feedback & Input:

- Request for Information
- NIH Staff survey
- IC White Papers
- Internal Town Hall Meetings
- External Consultation Meetings
- Data Analysis
- Internal and External Working Groups

Peer Review Oversight Committee (PROC) Established Working Groups:

1. Engage the Best Reviewers
2. Improve the Quality and Transparency of Review
3. Ensure Balanced and Fair Reviews Across Scientific Fields and Career Stages
4. Continuous Review of Peer Review

Identified Key Recommendations

Outline of Changes

January 2009

- Phase out of A2 applications
- Identification of Early Stage Investigator (ESI) R01 applications

May/June 2009 Reviews

- Enhanced review criteria
- New scoring system
- Criterion scoring
- Structured critiques
- Score order review
- Clustering of New Inv. Applications

January 25, 2010 Submissions

Priority Area 2 – Improve the Quality and Transparency of Review

- Restructured Applications
- Shorter Page Limits and New Instructions

Determination of New Application Status

- **Expected to be substantially different in content and scope with more significant differences than are normally encountered in a resubmitted application.**
  - **should include substantial changes in all sections of the Research Plan, particularly in the Specific Aims and the Research Strategy sections.**
  - **should be fundamental changes in the questions being asked and/or the outcomes examined.**
  - **should produce a significant change in direction and approach for the research project.**
- **Rewording of the Title and Specific Aims or incorporating minor changes in response to comments of reviewers in the most recent Summary Statement does not constitute substantial changes in scope, direction or content.**

- **http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-080.html**

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/

Enhanced 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

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-025.html

9-Point Scoring Scale

Impact	Score	Descriptor
High Impact	1	Exceptional
	2	Outstanding
	3	Excellent
Moderate 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 an average 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.

Excerpt from a Critique Template

1. **Significance**	Please limit text to ¼ page
Strengths • • • Weaknesses • • •	

- **List major strengths and weaknesses that influenced the overall impact/priority score**

Restructured Applications

Goal: Align structure and content of applications with Review criteria and improve efficiency and transparency of the review process

- **Application forms revised in three sections:**
  - **Research Plan**
  - **Biographical Sketch**
  - **Resources and Facilities**
- **Shorter page limits implemented for many programs**

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**

Shorter Page Limit Guide

Section of Application	Page Limits
Introduction for Resubmission Application	**1**
Specific Aims	**1**
Research Strategy: R03, R13/U13, R21, R36, R41, R43, Fellowships (F), SC2, SC3	**6**
Research Strategy: R01, single project U01, R10, R15, R18, U18, R33, R24, R34, U34, R42, R44, DP3, G08, G11, G13, UH2, UH3, SC1	**12**
Biographical Sketch	**4**

* Page limits may vary for other funding mechanisms.
Check Funding Opportunity Announcement:
http://enhancing-peer- review.nih.gov/page_limits.html

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
- **Review Criteria at a Glance**
  http://grants.nih.gov/grants/peer/guidelines_general/Review_Criteria_at_a_glance.pdf

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

- **Resources for Applicants**
  http://www.csr.nih.gov/ResourcesforApplicants
- **CSR Study Section Rosters**
  http://www.csr.nih.gov/committees/rosterindex.asp
- **Review Group Meeting Dates**
  http://www.csr.nih.gov/Committees/meetings/ssmeet1.asp