

Overview of the NIH Peer Review Process for Grants and Update on the New Application Format

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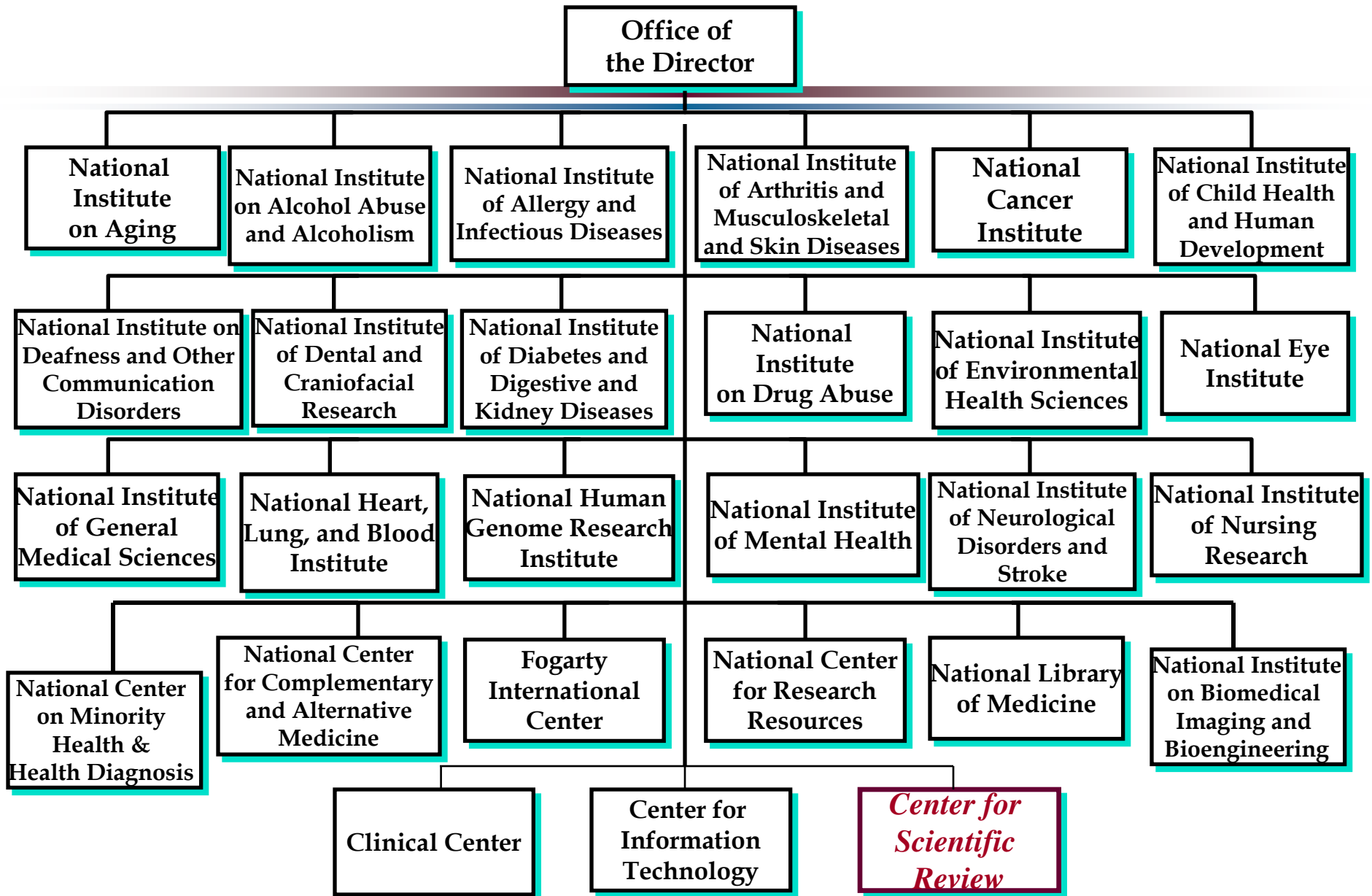
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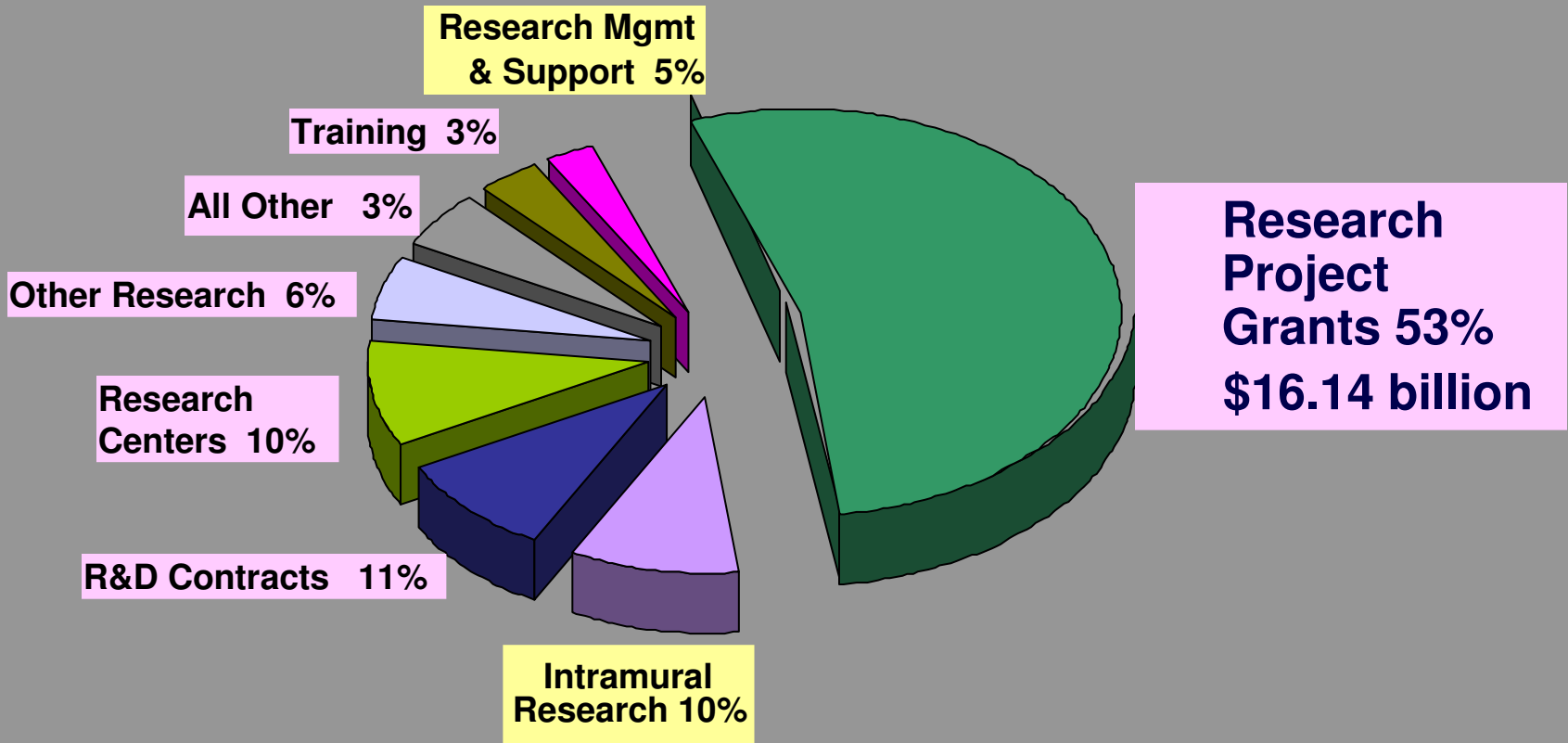
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National Institutes of Health



FY 2009 NIH Budget \$30.553 Billion



Key NIH Staff Involved in the Extramural Grants Process

- **Scientific Review Officer (SRO) (PhD or MD)**
 - In NIH Center for Scientific Review *and* each NIH Institute/Center
 - Organizes and manages scientific review groups (peer review committees/"study sections")
 - Prepares summary statements documenting the review
- **Program Officer/Director (PhD or MD)**
 - In NIH Institutes/Centers
 - Manages a portfolio of awarded grants/contracts
 - Monitors scientific progress of grants/contracts
- **Grants/Contracts Management Officer**
 - In NIH Institutes/Centers
 - Fiscal stewardship of portfolio of awarded grants/contracts
 - Monitors financial progress of grants/contracts

Terminology related to NIH Grant Applications

- **New** = First submission of an application
- **Resubmission** = Amended version of a previously submitted but unfunded application
 - NIH now allows ONE resubmission
 - Must address changes made
- **Renewal** = Request to extend the project period of an awarded grant
- **Revision** = Request for supplemental funds to expand an ongoing awarded grant
- **Corrected** = Fixing errors or warnings noted in Grants.gov or eRA validation process

Most NIH Applications are Submitted Electronically through Grants.gov

- NIH uses SF424 (Research and Related [R&R]) form
 - Forms generated by Grants.gov for cover page, administrative information, budget
 - PDF attachments for biosketches, research plan, other narrative sections, literature cited, collaboration letters, etc
- **eRA Commons** – the DHHS electronic system for receiving applications and transmitting review and award information to PIs and applicant institutions
- Institutions must register in both Grants.gov and eRA Commons
 - Institutions register in Grants.gov
 - Institutions register institution and their Principal Investigators in eRA Commons

Most NIH Applications are Submitted Electronically through Grants.gov

- Research project grants (R01, R03, R21, etc), resource grants, Fellowship (Fs), individual career development (K series), SBIRs
- Training (T32) and career development program (K12, K30) applications will transition on January 25, 2010
- Complex multi-component applications (P01, P30, P41, P50, M01, “U series”, etc) still submitted on paper on PHS 398
- See <http://era.nih.gov/ElectronicReceipt/> for timeline, FAQs, training materials, tips, contacts

Electronic Submission of Applications through Grants.gov

- Applications **must** be in response to an **open Funding Opportunity Announcement (FOA)** in Grants.gov
 - “Parent FOAs” = generic “umbrella” FOAs for “investigator initiated” applications – listed at [http://grants.nih.gov/grants/guide/parent announcements.htm](http://grants.nih.gov/grants/guide/parent_announcements.htm)
 - Specific science announcement (PA, RFA)
 - *NIH Guide for Grants and Contracts* provides link to correct FOA
 - Download specific application package with forms and instructions from FOA within Grants.gov.

Always download “fresh” to ensure that you have the latest version of the Grants.gov forms!

Parent FOAs for Common NIH Investigator-Initiated Applications

Parent FOA Title	Current Announcement Number	NIH Activity Code
Research Project Grant	PA-07-070	R01
Small Research Grant	PA-06-180	R03
Exploratory/Developmental Research Grant	PA-06-181	R21
Mentored Clinical Scientist Research Career Development Award	PA-09-042	K08
NIH Pathway to Independence Award (K99/R00)	PA-09-036	K99/R00
Small Business Innovative Research Grant	PA-06-120	R43/R44

**Note: Some NIH Institutes/Centers do not accept applications
submitted under the R21 and R03 Parent FOAs**

Science-Specific NIH Funding Opportunity Announcements

- **Program Announcement (PA)**
 - New or ongoing interest of one or more NIH Institutes/Centers
 - Addresses a relatively broad field/category of research
 - Usually no set-aside budget
 - Usually submit on regular receipt dates for mechanism
 - Usually regular review criteria for type of applications
- **Request for Applications (RFA)**
 - New or ongoing interest of one or more NIH Institutes/Centers
 - Addresses a well defined area of research
 - Set-aside budget for RFA applications
 - Submit on special, one time only receipt date
 - Often special eligibility and/or review criteria
 - Often special application format and/or submission instructions

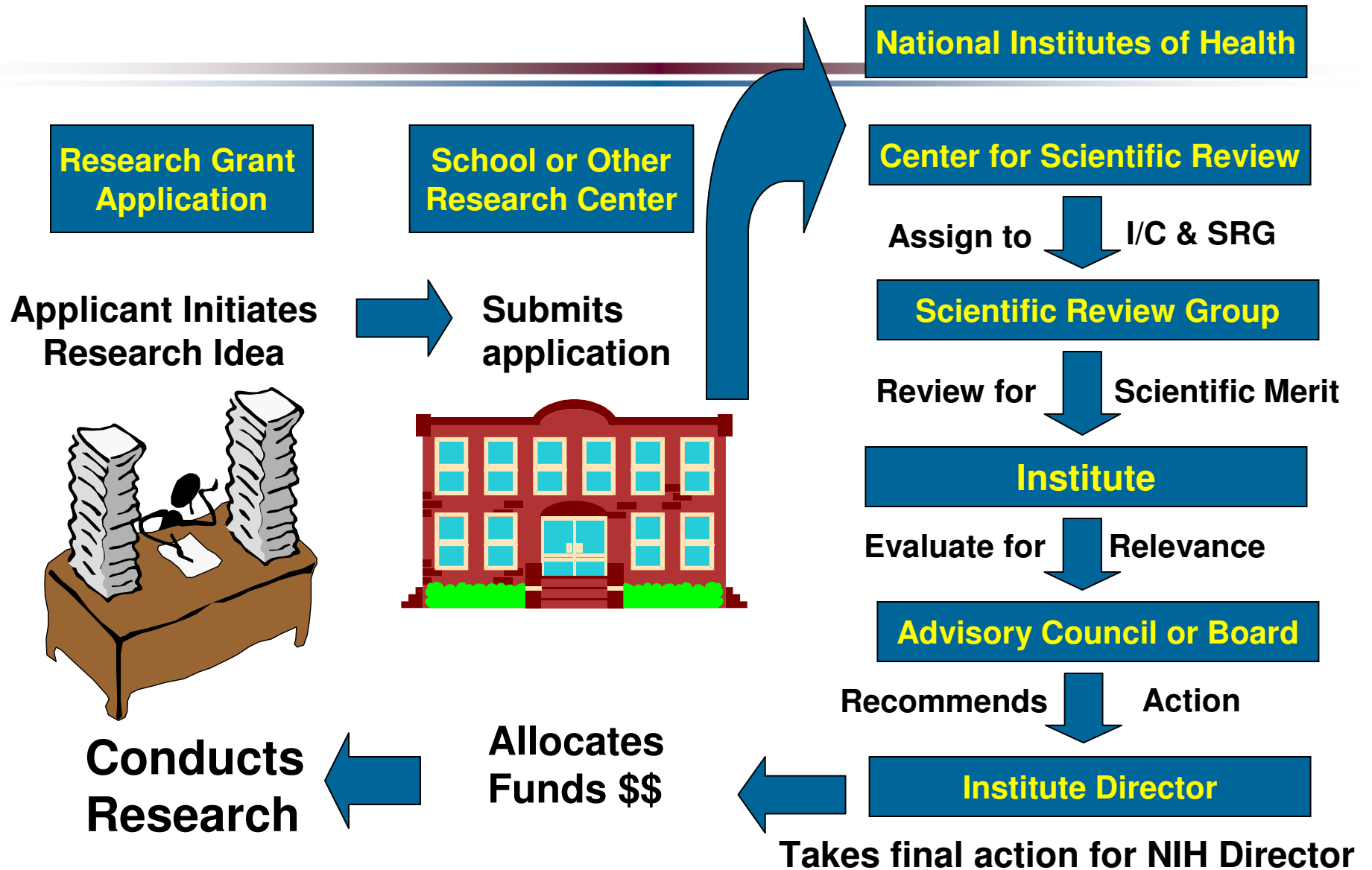
Electronic Submission of Applications through Grants.gov

- Principal Investigators prepare application
 - Adobe forms for Face Page, administrative information, budget
 - Separate PDF attachment for each narrative section of the application (Project Narrative, Budget Justification, Research Plan, Literature Cited, Human Subjects, Animal Welfare, Inclusion of Women/Minorities/Children)
- Authorized institutional official submits application
- Grants.gov and eRA Commons electronically validate forms and attachments
 - Applications with “errors” are rejected
 - You may submit a corrected application by the receipt date
- You may view “assembled” application in eRA Commons
 - You will see what the reviewers will see
 - Call eRA Help Desk if there are assembly problems

Multiple Principal Investigators (PIs)

- More than one PI may be designated for projects that require a “team science” approach
- Application must include a “Leadership Plan”
- Must designate “Contact PI” for communications with NIH
- Multiple PI option not available for career development (K) or fellowship (F) applications
- See http://grants.nih.gov/grants/multi_pi/index.htm

NIH SUBMISSION AND AWARD PROCESS

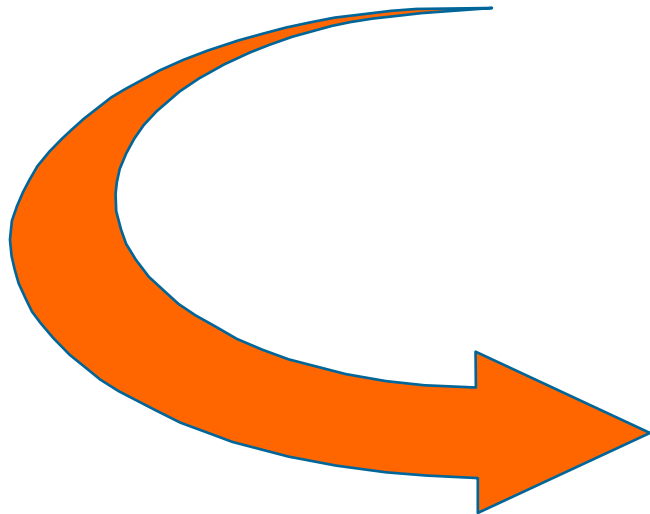


NIH Dual Review System for Grant Applications

First Level of Review

Scientific Review Group (SRG)

- Scientific merit/impact review
- Rate/score applications and recommend appropriate budget and duration of award
- *Does NOT make any funding decisions*



Second Level of Review

Institute Advisory Council/Board

- Assesses quality of SRG review of applications
- Makes recommendations to Institute staff on funding
- Evaluates Institute program priorities and relevance
- Advises on Institute policy

Enhancing Peer Review at NIH

(see <http://enhancing-peer-review.nih.gov/index.html> for more info)

- Wide ranging self assessment - begun in June 2007
 - Fundamental structure, timeline, organization of the NIH peer review process has not changed
 - Optimize efficiency, effectiveness, transparency of review process
 - Reduce administrative burden for applicants and for NIH
 - Internal and External working groups, with input from investigators, professional societies, advocacy groups
- March 2008 recommendations now being implemented:
 - Early Stage Investigator – less than 10 yrs from terminal degree
 - Fund best science earlier - eliminate review “queue” effect by allowing only one resubmission application
 - Enhanced review criteria – emphasis on *impact*
 - New 1 – 9 scoring system
 - Sub-scores for each “core” review criterion for all applications
 - Shorter, reformatted grant applications starting in Jan 2010

Three Overlapping NIH Grant Cycles/Yr: Submit When You are Ready

Jan-May May-Sept Sept-Jan	Receipt Dates
May-July Sept-Nov Jan-Mar	Review Meetings
Sept-Oct Jan-Feb May-June	Advisory Councils/Boards
Dec 1 Apr 1 July 1	Earliest Possible Start Date

Major NIH Application Receipt Dates

- **New R01** 5th of Feb, June, October
- **New Career Development**
(K series) 12th of Feb, June, October
- **New R03, R21** 16th of Feb, June, October
 - R01 renewals and K/R resubmissions due one month later
(March, July, November)
- **All P series/T32s** 25th of Jan, May, September
- **All F series** 8th of April, August, Dec

(see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-001.html> for complete list)

NIH Center for Scientific Review (CSR)

- Central receipt point for all grant applications for NIH and other DHHS components
- Assigns applications to NIH Institute/Center as potential funding component
- Manages ~200 Scientific Review Groups (“Study Sections”)
- **You may request study section and/or multiple Institute/Center assignment in cover letter submitted with application**
 - NIH Institute/Centers share interest areas, so dual/multiple assignments are common

Assignment of Applications for Review

- Topic/research area
- Past review history (if any) of application
- Type of Application
 - CSR Study Sections
 - Research project grants (R01, R03, R21)
 - Small business innovation research
 - Pre/Postdoctoral Fellowship (F) applications
 - Institute/Center review offices
 - Career development (K series) and Training
 - Complex and special types of grants
 - Multi-site clinical trials
 - Responses to RFAs, specialized PAs
 - Other “mission-targeted” applications

What Happens In A Study Section Meeting?

- SRO is Designated Federal Official for review meeting
 - Recruits reviewers
 - Provides orientation re: conflict of interest and confidentiality
 - Ensures reviewers follow correct policies, process, review criteria
- Study Section Composition
 - Usually 15 - 25 members, primarily from academia
 - Senior investigators in a broad range of related fields
 - Standing members + Ad hoc reviewers recruited for special expertise
- 60 - 100 applications reviewed at each meeting
 - SRO assigns at least 3 reviewers per application
 - Reviewers get applications ~1 month before meeting, and submit preliminary critiques and scores
 - Meetings last 1 – 2 days

What Happens In A Study Section Meeting?

- Applications in “lower half” identified, not discussed
- For applications that are discussed
 - Persons with conflicts of interest excused
 - Assigned reviewers give preliminary scores
 - Each assigned reviewer lists strengths and weaknesses re: each review criterion
 - Questions for assigned reviewers, full panel discussion
 - Discussion of human subjects protection, gender, minority, and children inclusion, animals
 - Assigned reviewers recommend final score
 - All panel members (except those in conflict) score privately; must speak up if outside recommended range
 - Budget recommendations

“Core” Review Criteria for Research Project Grants

- **Significance**: Does the project address an important problem or a critical barrier to progress in the field? How will scientific knowledge, technical capability and/or clinical practice be advanced?
- **Investigator(s)**: Are they well suited to the project?
 - If Early Stage or New Investigators, do they have appropriate experience and training?
 - If established, do they have record of accomplishments?
 - Is the Multiple PI leadership plan appropriate?
- **Innovation**: Does the application challenge and seek to shift research or clinical practice paradigms by using novel theoretical concepts, approaches, methodologies, instrumentation or interventions?

“Core” Review Criteria for Research Project Grants

- **Approach**: Are the overall strategy, methods, analyses well-reasoned and appropriate for the aims? Are potential problems, alternatives, and benchmarks addressed?
 - For early stage projects, will the strategy establish feasibility? How will particularly risky aspects be managed?
 - For clinical research, are the plans for protection of human subjects and inclusion of minorities, women, and children appropriate?
- **Environment**: Will the institutional environment, support, equipment, etc contribute to the probability of success? Will the project benefit from unique features of the environment, subject populations, or collaborations?

Each assigned reviewer gives a “subscore” for each of these “core” review criteria: 1 (exceptional) – 9 (poor)

SCORE	DESCRIPTOR	ADDITIONAL GUIDANCE ON STRENGTHS/WEAKNESSES
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

Minor Weakness: Easily addressable weakness that does not substantially lessen impact

Moderate Weakness: A weakness that lessens impact

Major Weakness: A weakness that severely limits impact

Other Review Criteria for Research Project Grants

- Additional Review Criteria – Affect the overall impact score
 - Human Subjects Protection
 - Data and Safety Monitoring Plan required for ALL clinical trials
 - Plans for Inclusion of Women, Minorities and Children in Clinical Research
 - Vertebrate Animal Protection
 - Any RFA-specific criteria, if applicable
 - Resubmission Applications – changes made in response to previous review
 - Renewal Applications – progress in current funding period
 - Biohazards
- Additional Review Considerations – Do not affect the overall impact score
 - Appropriateness of the Budget
 - Resource sharing plans

Scientific Review Group Options

- **Not Discussed**
 - Application not in top half of all applications
- **Not Recommended for Further Consideration (NRFC)**
 - Lacks significant and substantial merit and/or serious ethical problems re: Human Subjects or Animals
- **Deferred**
 - Review Committee needs more information to decide on the application
 - SRO will contact applicant to obtain needed info
- **Impact/Priority Score Assigned**
 - 1 (exceptional) to 9 (poor)
 - Each committee member not in conflict scores in whole numbers

Overall Impact/Priority Score and Percentile Ranking

- Overall impact/priority score
 - **Likelihood that project will exert a sustained, powerful influence on the research field(s) involved**
 - Emphasis on each core review criterion may vary
 - NOT just average of subscores for 5 core criteria
 - Average impact scores from all cmte members X 10
 - Whole numbers: 10 (best) – 90 (worst)
- Percentile = rank of application score relative to all applications reviewed by the Study Section in current and past 2 review cycles
 - Range = 1st (best) – 100th (worst)
 - Rounded to nearest whole number

The Summary Statement

Documents the Outcome of the Review

- Prepared by SRO after review is completed
- Contains:
 - Impact/Priority Score & Percentile Ranking (if application discussed)
 - Codes for Human Subjects protection, gender, minority, children
 - Resume and Summary of Discussion
 - Criterion sub-scores and essentially unedited critiques from assigned reviewers
 - Budget recommendations and Administrative Notes
 - Roster of reviewers
- Forwarded to Program staff in NIH Institute/Center and Advisory Council/Board
- PI can retrieve priority score, percentile ranking and summary statement through the NIH eRA Commons
- PI should discuss prospects for award or need to revise with the NIH Program Officer listed on the Summary Statement

What Determines Which Applications are Awarded?

- **Impact/priority score and/or percentile ranking**
 - Each NIH Institute/Center sets its own “paylines”
 - Paylines vary for different types of grants
 - More liberal payline for New/Early Stage Investigators
- **Programmatic considerations** of the awarding NIH Institute/Center
 - Balance of models, geographic sites, approaches, etc, in portfolio
- **Availability of funds**
 - Funds for “competing” grant awards limited -- most of budget already committed to continuing grants and programs
 - Flat budget + increased number of applications FY 05 - 08
 - ~ 3.7% increase in base budget for FY 2009
 - ARRA Stimulus funds for FY 2009/2010
 - Budget increases for FY 2010 and beyond??

Shortened Resubmission Cycle for R01s from Early/New Investigators

- Special receipt dates (21st of July, Nov, March) for resubmitted R01* applications
 - Allows about a month to revise and resubmit for the very next meeting of the same study section
 - Saves about 4 months in turnaround time
 - Appropriate for projects with easily addressable problems
 - PI must decide if weaknesses cited in Summary Statement are amenable to “quick fix”
- See: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-083.html>

Last Phase of Enhancing Peer Review: New Application Format as of January 25, 2010

- Goals:
 - Align application sections with review criteria
 - Make applications more concise
 - Focus reviewers on strategy, impact vs details of methods
- New R01 format also applies to projects within multi-project applications (P01s, P50)
- All NIH FOAs are currently being updated
- **Required new application packages will be uploaded to FOAs about December 1st**
- **Parent FOA numbers will change!**
- See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-149.html> for more information.

Application Components Not Changing

- Face page/administrative sections
- Budget components/forms
- Specific Aims – 1 page
- Human Subjects sections – no page limit
 - Address all required points
 - Address power calculations/statistical issues
 - Provide details about subject populations, eligibility criteria, enrollment strategies
- Animal Welfare – no page limit
 - Address all required points
 - Address power calculations/statistical issues
 - Derivation of specific models, breeding strategies, etc
- Appendix rules and limitations

Reformatted as of January 25, 2010

- Biosketch – Customized to each application
 - Personal statement – Experience/qualifications for role
 - Should limit to 15 publications – based on most important, most recent, most relevant to this project
- Resources – New sections
 - Describe how scientific environment contributes to probability of success
 - If PI is Early Stage Investigator, describe institutional investment in his/her success
 - Resources for classes, training, travel for professional development
 - Collegial support/guidance, institutional career enrichment programs
 - Logistic, administrative and/or salary support

Reformatted and Shortened as of January 25, 2010

- Introduction to Resubmission – 1 page
 - Address previous overarching issues vs point-by-point
- Research Strategy: R01 = 12 pgs; R03/R21 = 6 pgs
 - Significance
 - Innovation
 - Approach

Address “questions” under each respective review criterion

- Preliminary Studies (for new applications)
- Progress Report (for renewals and supplements)
- Write critically, concisely, specifically
 - Do not repeat information different sections - Provide clear references to information in other sections
 - Emphasize rationale, strategies, analyses, criteria for moving to next aim

Selected Web Sites of Interest

- **National Institutes of Health** (<http://www.nih.gov>)
 - NIH Office of Extramural Research homepage, with links to the NIH Guide, grants policy information, and resources for new investigators: <http://grants1.nih.gov/grants/oer.htm>
 - Overview of NIH Extramural Research, with links to tools and FAQs: <http://grants1.nih.gov/grants/welcome.htm#introduction>
 - NIH Electronic receipt <http://era.nih.gov/ElectronicReceipt/>
 - Enhancing peer review <http://enhancing-peer-review.nih.gov/index.html>
- **NIH Center for Scientific Review**
(<http://www.csr.nih.gov>)
 - Links to Resources for Applicants, standing Study Section rosters, policy information, review procedures and review criteria, video of mock study section, and advice for investigators submitting clinical research applications
- **Grants.gov** (<http://www.grants.gov>)