How to Be More Competitive in the NIH Peer Review Process for Grants
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Clinical Research Projects are Hard to Design Well

Overall success rate of clinical research projects slightly lower than success rate for basic research projects

Extensive NIH analysis: Difference not due to:
- Higher budgets for clinical research
- Review panel assignment
- Number or % of clinical applications in review meeting
- Number or % of clinical scientists on review panel

Clinical projects are harder to design well
Clinicians may “give up” rather than revise
Topics for Today
Overview of NIH Peer Review Process
Review criteria for research project grants
Career Development award mechanisms
The NIH Loan Repayment Program for Clinical Researchers
Format for Research Project applications
Hints for preparing a stronger application
FY 2011 NIH Budget
$30.92 Billion

Pie chart showing the breakdown of NIH budget
NIH Dual Review System for Grant Applications
Second Level of Review

First Level of Review
Scientific Review Group (SRG)
Scientific merit review
Rate/score applications and recommend appropriate budget and duration of award
Does NOT make any funding decisions

Advisory Council/Board
Assesses quality of SRG review of grant applications
Make recommendation to Institute staff on funding
Evaluate program priorities and relevance
Advise on Institute policies
NIH SUBMISSION AND AWARD PROCESS

Flow chart showing the NIH award and submission process
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
Liaison between applicants and reviewers

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
Most NIH Applications are Submitted Electronically through Grants.gov

Grants.gov – on-line portal to find and apply for most Federal grants

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 SAM (System for Award Management) and eRA Commons

Institutions register in SAM
Institutions register institution and their Principal Investigators in eRA Commons
Electronic Submission of Applications through Grants.gov

Applications **must** be in response to an open Funding Opportunity Announcement (FOA) in Grants.gov

“Parent FOAs” listed at http://grants.nih.gov/grants/guide/parent_announcements.htm

Science- and I/C mission-specific FOAs on various topics

**NIH Guide for Grants and Contracts** (http://grants.nih.gov/grants/guide/) provides link to correct FOA

Download specific application package with forms and instructions from the FOA within Grants.gov.

**Always download application package “fresh” so you have the latest version of the Grants.gov forms!**
Parent FOAs for Common NIH Investigator-Initiated Applications

Graphic: Chart

Note: Some NIH Institutes/Centers do not accept applications 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 (I/Cs)
- Addresses a relatively broad field/category of research
- Usually no set-aside I/C 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 (I/Cs)
- 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
SF424 (Research and Related [R&R]) forms

All single component research grants (Rs), fellowships (Fs), career development (K), training (T and D), conferences, SBIRs

Grants.gov generates Adobe forms for cover page, administrative information, budget
PI uploads PDF attachments for biosketches, research strategy & other narrative sections, literature cited, letters of collaboration

See http://era.nih.gov/ElectronicReceipt/ for FAQs, training materials, tips, contacts for help

Complex multi-component applications (P01, P30, P50, U19, etc) still submitted on paper via PHS 398 form
Electronic Submission of Applications through Grants.gov

Principal Investigators prepare application
Authorized institutional official submits application to Grants.gov
Grants.gov and eRA Commons electronically validate forms and attachments
   Applications with “errors” are rejected
Submit 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
Available for most types of research project grants
  Must designate “Contact PI” for communications with NIH
  Multiple PIs do not need to devote equal effort
  Application must include a section describing the “Leadership Plan”
Multiple PI option not available for career development (K) or fellowship (F) applications
See
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
- Reviewers submit preliminary critiques and scores
- Meetings last 1 – 2 days
What Happens In A Study Section Meeting?

Applications discussed in preliminary impact score order
  Persons with conflicts of interest excused
  Assigned reviewers give preliminary scores
  Each assigned reviewer lists strengths and weaknesses re: each criterion
  Questions for assigned reviewers, full panel discussion
  Discussion of human subjects protection; gender, minority, and children inclusion; animal welfare
  Assigned reviewers recommend final score
  All panel members (except those in conflict) score privately; must speak up if outside recommended range
  Budget recommendations

Bottom half of applications not discussed
“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?
- If Multiple PIs, is the 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?

Before the review meeting, each assigned reviewer gives a “subscore” for each of these 5 “core” review criteria: 1 (exceptional) – 9 (poor)
Graphic: Chart
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/foreign institutions/select agents
Scientific Review Group
Options

Impact/Priority Score Assigned
  1 (exceptional) to 9 (poor)
  Each committee member not in conflict scores in whole numbers

Deferred (rare)
  Review Committee needs more information to decide on the application
  SRO will contact applicant to obtain needed info

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
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 sub-scores 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 discussed)
- Codes for Human Subjects protection, gender, minority, children
- Resume and Summary of Discussion (if discussed)
- Criterion sub-scores and essentially unedited critiques from assigned reviewers
- Budget recommendations and Administrative Notes
- Roster of reviewers

Used by Program staff in NIH Institute/Center and Advisory Council/Board to make funding decisions
Retrieve score, percentile and summary statement through the NIH eRA Commons
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, diseases, 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
Shortened “Next Cycle” Option for R01s from New/Early Stage Investigators

Special receipt dates (10th of August, December, April) for resubmission 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:
Shortened “Next Cycle” Option for R01s from New/Early Stage Investigators

Graphic: Bar graph
Format for Research Project Application

Application sections align with review criteria
Concise format focuses reviewers on strategy, impact vs details of methods
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, alternatives if exp’ts don’t work
R01 format also applies to projects within multi-project applications (P01s, P50)
Format for Research Project Application

Introduction to Resubmission – 1 page
  Address overarching issues/changes vs point-by-point

Specific Aims – 1 page
  State overall objective
  List aims
  Describe potential impact on the field

Research Strategy: R01 = 12 pgs;
R03/R21 = 6 pgs
  Significance
  Innovation
  Approach
  Preliminary Studies (for new applications)
  Progress Report (for renewals and supplements)
Format for Research Project Application

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
  Describe how scientific environment contributes to probability of success
  If Early Stage Investigator, describe institutional investment in PI’s success
    Resources for classes, training, travel for professional development
    Collegial support/guidance, institutional career enrichment programs
    Logistic, administrative and/or salary support
**Other Application Components**

Face page/administrative sections
Budget components/forms
Human Subjects sections – no page limit

- Address all required points
- Address power calculations/statistical issues
- Provide details about subject populations, eligibility criteria, enrollment/retention 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**

*Individual Career Development Awards*  
(See NIH “K” Kiosk at...
K01 - Mentored Research Scientist Development Award (PA-10-056)  
Usually for Ph.D.’s, for basic research; not accepted by all NIH Institutes/Centers

K02 - Independent Scientist Award (PA-10-057)  
Additional time/effort support for new researcher with R01

K07 - Academic Career Award (PA-10-058)
K08 - Mentored Clinical Scientist Development Award (PA-10-059)  
For clinicians to get basic/laboratory research training

K22 – Career Transition Awards  
For postdoctoral fellows transitioning to their first faculty position  
See specific FOAs from NCI, NIAID, NHLBI, NIAAA, NIAID, NINR

K23 - Mentored Patient-Oriented Research Career Development Award (PA-10-060)
K24 - Mid-Career Award in Patient-Oriented Research (PA-10-061)
K25 – Mentored Quantitative Research Development Award (PA-10-062)
K99/R00 - Pathway to Independence (PI) Award (PA-10-063)  
For postdoctoral fellows with no more than 5 yr of training  
1 - 2 yr mentored phase followed by 3 yr independent phase
Format for Career Development Award Applications

Biosketches and Resources as already described for R01 applications

Introduction to resubmission – 1 page

Specific Aims – 1 page

Candidate Information + Research Strategy sections – total of 12 pages

  Candidate’s Background
  Career Goals and Objectives
  Career Development/Training Activities

Training in Responsible Conduct of Research

Research Strategy, including preliminary studies
Review Criteria for Individual Career Development Awards

Individually scored review criteria
  Candidate
  Career development plan
  Research plan
  Mentor(s), Consultant(s), Collaborator(s)
  Environment

Additional review criteria (Human Subjects, Animals, resubmission, biohazards), as applicable

Overall Impact Score: Likelihood for the candidate to maintain a strong research program

Additional review considerations: Training in responsible conduct of research, select agents, resource sharing plans, budget
The NIH Loan Repayment Program: Special Opportunity for Clinical Researchers

Designed to attract health professionals into research

Clinical
Pediatric
Health disparities
Contraception and fertility

Also a program for researchers from disadvantaged backgrounds

Repays up to $35,000 per year (for 2 yrs) of qualified educational debt (student loans) in exchange for 2 – 3 yr commitment to research

Must be US citizen

One receipt date per year, special application form

See http://lrp.nih.gov/about/extramural/index.htm
Tips for Better Grantsmanship
Understand the “Psychology” of the Review Process

Reviewers are:
- Over committed, over worked and tired
- Inherently skeptical and critical
- “Informed strangers”

A happy reviewer is likely to be more positive, so make their job easier:
- Flow diagrams, charts, figures
- Well organized, clearly written application

Avoid things that reflect poorly on PD/PI:
- Not following instructions
- Putting information in the wrong section, omitting or mislabeling references/figures
- Dense text, tiny fonts, no “white space” on pages
- Spelling, grammar, and math errors, etc.
Preparing to Write a Grant Application

Critically assess yourself
Do you have the necessary expertise, resources, personnel, and preliminary data to be competitive?

Assess the competition
Who are the important contributors to the field? (remember, they might end up being your reviewers)
What have they accomplished?
Search the literature and the RePORTER NIH database of funded grants in the field (http://projectreporter.nih.gov/reporter.cfm)

Assess the potential impact of your project
What has already been done/reported/funded in your area? What are the “gaps”?
How can you take what's been done a step farther?
Choosing Your Research Project

What makes a research project likely to have a high impact?

- Addresses an important problem clearly
- Potential to lead to seminal new observations or new ways of thinking
- Lays the foundation for further research in the field
- Addresses a difficult problem in a way that seems simple in retrospect, making reviewers wonder why they didn't think of the idea themselves
- All aspects of the project are clearly linked
Preparing the Research Plan

Limit research plan to 2 - 4 closely related specific aims
Explicitly state the rationale for the proposed studies and the proposed methods
Use flow diagrams for overview, and for complex experiments and protocols
Include easy to follow tables and figures
Address priorities if patients, reagents or resources will be limited
Include plans and methods for data analysis and interpretation
Involve the statistician EARLY in project design
Excite reviewers about where results will lead
Key Features of Successful Applications

Hypothesis
- A meaningful hypothesis AND a means of testing it
- A sound rationale for the hypothesis

Preliminary Data
- Documents feasibility of the proposed project
- Shows training for research proposed & ability to interpret results
- Include alternative interpretations and address limitations of methods

Well Organized Research Plan
- Aims focused - related to each other and the hypothesis
- Rationale for methods proposed, with alternatives addressed
- Research flow and priorities clearly indicated
- Sufficient experimental detail to show you understand methods
- Emphasize MECHANISM - avoid “descriptive data gathering”
Key Features of Successful Applications, con’t

Biosketches
  Address your qualifications to carry out the work proposed
  Don’t “pad” with lots of “in preparation” manuscripts
  Add a senior collaborator, if needed, to provide expertise you lack

Literature Cited/Bibliography
  Be thorough, but critical, in citing previous work in the field

Description (Project Summary in SF 424 applications)
  Most read part of the application
  Basis for referral to study section and funding Institute/Center
  Write it last, after the Research Plan is finished
  State problem, specific aims, types of methods to be used

Letters of Collaboration
  Should be strong and definitively state what will be provided
Most Common Reasons for “Not Discussed” or Not Recommended for Further Consideration

Preliminary data do not support the hypothesis
Aims don’t address hypothesis
Diffuse/unfocused research plan
Descriptive or superficial research plan
Rationale for choosing proposed methods not clear
Experimental design/flow not clear
Flaws in experimental approaches – especially inadequate controls
Models not relevant to human situation
Inadequate statistical power
Unrealistically large amount of work proposed
Project is confirmatory/doesn’t address data in literature
Lack of experience in essential methods
Serious risks to human subjects or animals
Make Sure Your Application is Complete and Correct as Submitted

START EARLY – Registering in SAM and eRA Commons AND planning the science
Read instructions thoroughly and follow them carefully
   Especially important for electronic applications
   Avoid validation errors in Grants.gov and eRA Commons

Allow time for frank feedback on aims, research strategy from senior colleagues with review experience

Correction/supplemental materials allowed only for unforseen administrative issues
   Loss of investigator, news of article accepted for publication
   New data, correction of omissions or errors in text, figures, new letters of collaboration not permitted
NIH Program and Review Staff Can Help

Know the NIH program officer(s) in your field

- Check programs in several NIH Institutes and Centers
- Information about upcoming initiatives, opportunities, “gap” areas
- Information about potential collaborators, NIH resources
- Explain NIH policies, procedures, award mechanisms, eligibility requirements
- Advice in revising unfundable applications

Know the Peer Review System and your SRO

- Review criteria and receipt/review schedules
- Explain NIH policies, procedures, award mechanisms, eligibility requirements
- Problems with referral or review

Use the NIH website to get latest forms and information about peer review policies and procedures
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
NIH Electronic receipt http://era.nih.gov/ElectronicReceipt/
Enhancing peer review http://enhancing-peer-review.nih.gov/index.html
Links to homepages for each NIH Institute and Center http://www.nih.gov/icd/

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)