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 2015 NIH Budget
$30.31 Billion

NIH Dual Review System for Grant Applications

Second Level of Review

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

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 or ASSIST

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/funding/index.htm/) 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

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

Most research grants are now submitted electronically

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://grants.nih.gov/grants/how-to-apply-application-guide.htm to access a How to Apply – Application Guide

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 http://grants.nih.gov/grants/multi_pi/index.htm

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?

"Core" Review Criteria for
Research Project Grants

Significance: Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? 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 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?

"Core" Review Criteria for
Research Project Grants

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?

"Core" Review Criteria for
Research Project Grants

Approach: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

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?

"Core" Review Criteria for
Research Project Grants

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)

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

Other Review Criteria for
Research Project Grants

Additional Review Considerations – Do not affect the overall impact score

Appropriateness of the Budget

Resource sharing plans

Foreign institutions

Select Agent Research

Authentication of Key Biological Resources

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources

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: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-001.html

Shortened "Next Cycle" Option
for R01s from New/Early Stage Investigators

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

Briefly describe up to five of your most significant contributions to science. While all applicants may describe up to five contributions, graduate students and postdoctorates are encouraged to consider highlighting two or three they consider most significant.

Format for
Research Project Application

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 http://grants.nih.gov/training/careerdevelopmentawards.htm)

K01- Mentored Research Scientist Development Award (PA-14-044)

Usually for Ph.D.'s, for basic research; not accepted by all NIH Institutes/Centers

K02 - Independent Scientist Award (PA-14-045)

Additional time/effort support for new researcher with R01

K08 - Mentored Clinical Scientist Development Award (PA-14-046)

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, NIDCR, NIEHS, NIMH, NINDS, NHLBI

K23 - Mentored Patient-Oriented Research Career Development Award (PA-14-049)

K24 - Mid-Career Award in Patient-Oriented Research (PA-14-047)

K25 – Mentored Quantitative Research Development Award (PA-14-048)

K99/R00 - Pathway to Independence (PI) Award (PA-16-077)

For postdoctoral fellows with no more than 4 yr of training

1 - 2 yr mentored phase followed by 2 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://www.lrp.nih.gov/

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

See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-030.html

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://grants.nih.gov/grants/how-to-apply-application-guide.htm

Enhancing peer review http://enhancing-peer-review.nih.gov/index.html

Links to homepages for each NIH Institute and Center http://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices

Selected Web Sites of Interest

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)