Today’s Agenda: The Deep Dive into NIH Grants

- Plan Ahead, Get Prepared
  - What’s New in the Zoo?
  - Get Help from the Inside
  - Discover NIH’s Footprint in Your Area
  - Organize Your Team
  - Match Your Application to Mechanism and Institute

- Elements of the Grant Application
  - Specific Aims: your key to success
  - Research Strategy: helpful hints
  - Other Considerations
  - Funding Emerging Science, Technology Development

- Just Send It

- Now it’s our turn: The Review Process
  - Find the Best Review Committee
  - Understand the Assessment
  - Respond to the Evaluation
Plan Ahead, Get Prepared

- What’s new in the Zoo?
- Get Help from the Inside
- Discover NIH’s Footprint in Your Area
- Organize Your Team
- Match Your Application to Mechanism and Institute
Know Your Target

Federal Agencies in Science and Technology have different
✓ missions
✓ cultures
✓ rules
✓ levels of support
✓ expectations

But the same overall goal
✓ protect the security, health, and well being of Americans
✓ maintain knowledge and application superiority
✓ fuel the engine of US economic growth

Source: [AAAS](http://www.aaas.org/page/historical-trends-federal-rd)
Different Agencies: Different Cultures

- Research: basic to applied
- Development

- Spectrum of support: NSF, NIH, DARPA

- High Risk to High Feasibility

- Probability of success

- Entrepreneurial to Experienced

- PI/Team Qualifications
NIH FY16 Budget

NIH Divides most of its investment according to the interests of the component parts (i.e. Institutes or Centers), with 5% allocated to trans-NIH initiatives.

About 85% distributed via Extramural grants, contracts, cooperative agreements.

Total = $32 B
NIH “hot topics”

- Precision Medicine Initiative
- Discovery Science
  - BRAIN Initiative
  - Microbiome and health
  - Stem Cell Technology (tissue chips, regenerative medicine)
  - New Vaccines (Zika, Ebola, Flu, HIV...)
- Translating discovery into health
  - Antimicrobial Resistance
    - national database of germ genomes
    - prize for better diagnostics (w/BARDA)
    - antibiotics and vaccines
  - Alzheimer’s Disease
    - basic research
    - epidemiology for risk/protective genes
    - early diagnosis and progression
  - Accelerating Medicines Partnership (Alzheimer’s, type 2 diabetes, lupus, rheumatoid arthritis)
- Preparing a diverse and talented biomedical research workforce

How Does NIH Solicit Applications?

- **Federal Opportunity Announcements (FOA)** published through
  - the NIH Guide (http://grants.nih.gov/grants/guide/)
  - grants.gov

- **Parent Announcements** cover basic activity codes
  - investigator-initiated applications

- **Special Opportunities to fill gaps**
  - **Requests for Applications (RFA)**, a one-time call with set aside funds
  - **Program Announcement (PA)** highlights areas of focus
  - **Program Announcement with Special Review (PAR)** for special consideration and “protected” review
  - **Program Announcement with Set Aside (PAS)** essentially, an RFA with multiple receipt dates
Need Help with Your Proposal... Who Ya’ Gonna’ Call?

✓ about the scientific and technical aspects of your application...
  - Find them on the solicitation
  - See also the IC’s programmatic descriptions (http://www.nih.gov/icd/index.html).

✓ for questions during the review...
  - Listed on the eRA Commons link to your submitted proposal
  - See also the review group rosters at the CSR web site

✓ for help with the business aspects of a proposal...
  - Listed on the eRA Commons link to your submitted proposal
  - See also the IC’s programmatic descriptions (http://www.nih.gov/icd/index.html).

Program Director
Scientific Review Officer
Grants Specialist
NIH Program Officials: your primary contact

Pre-Application
- Assess the “fit” to the IC, Program(s)
- Start the conversation early: develop your ideas together
- Choose the right activity/mechanism
- Brief on Review Issues: Dos/Don’ts

Post Review
- Analyze the Summary Statement: deeper insights from the Review
- Understand the rating and assess the likelihood of funding
- BEWARE! Nothing is certain until you have it in writing

During the Award
- Discuss problems in execution (rebudgeting, rescoping, extensions...)
- Find an administrator to address unusual issues
- Brag about important discoveries

Anytime
- Arrange introductions so you can serve on advisory boards workshop panels, etc. to help set the research agenda
- Discover what’s New and Coming Soon in Funding Opportunities

Application → Review → Award

... improving health by leading the development and accelerating the application of biomedical technologies
NIH Institute/Center Web Sites

NIH OFFICES

**NIH Office of the Director (OD)**
The Office of the Director is the central office at NIH for its 27 Institutes and Centers. The OD is responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of all the NIH components. OD’s program offices include the Office of AIDS Research and the Office of Research on Women’s Health, among others.

Each NIH Institute/Center has a HOME PAGE

Model: http://www.xxxxxx.nih.gov

http://www.nibib.nih.gov/
Biomaterials Program Area

Staff Contact

Rosemarie Hunziker, Ph.D.

Description

This program supports the research and development of new or novel biomaterials that can be used for a broad spectrum of biomedical applications such as implantable devices, tissue engineering, imaging agents, and biosensors and actuators.

Research that is supported includes the design, synthesis, characterization, processing and manufacturing of these materials as well as the design and development of devices constructed out of these materials and their clinical performance.

Relevant Study Sections

Biomaterials and Biointerfaces (BMBI)
Does NIH Already Support My Interest Area?

NIH Searchable Databases Contain Abstracts of All Funded Projects

Search by
- MESH terms
- Key words
- Organizations
- States
- Investigators
- Mechanisms
- Solicitations
- Institutes
- Investigators
- ...
RePORTer Delivers a Treasure Trove...

There were 10 results matching your search criteria. Click on the column header to sort the results.

<table>
<thead>
<tr>
<th>Act</th>
<th>Project</th>
<th>Year Sub #</th>
<th>Project Title</th>
<th>Contact PI/Project Leader</th>
<th>Organization</th>
<th>FY</th>
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<td>CA165111</td>
<td>01A1</td>
<td>TUMOR ANTIGEN-SPECIFIC T-CELLS AND HEPATOCELLULAR CARCINOMA</td>
<td>KAPLAN, DAVID E</td>
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<td>MULTIFUNCTIONAL TROPOFILASTIN-SILK BIOMATERIAL SYSTEMS</td>
<td>KAPLAN, DAVID L</td>
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<td>KAPLAN, DAVID L et al.</td>
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**Project Information**

**Project Number:** 5R01EB014283-02  
**Title:** MULTIFUNCTIONAL TROPOELASTIN-SILK BIOMATERIAL SYSTEMS  
**Contact PI / Project Leader:** KAPLAN, DAVID L  
**Organization:** TUFTS UNIVERSITY MEDFORD  
**Program Official Information:**  
**Name:** HUNZIKER, ROSEMARIE  
**Email:** Click to view PO email address  
**Study Section:** Gene and Drug Delivery Systems Study Section (GDD)

**Other Information:**  
**DUNS Number:** 073134835  
**CFDA Code:** 286  
**Project Start Date:** 1-AUG-2012  
**Project End Date:** 31-JUL-2016  
**Budget Start Date:** 1-AUG-2013  
**Budget End Date:** 31-JUL-2014  
**Fiscal Year:** 2013  
**Award Notice Date:** 25 JUL 2013
Even broader functionality from Federal RePORTER

http://federalreporter.nih.gov/
How to Use RePORTER When Preparing New Grant Applications

Posted by Dr. James Onken on December 3, 2012
Post a Comment | View Comments (1) ↓

NIH offers two tools that can help you search for projects similar to the one you're thinking about. In this post, I'll take you on a quick tour of the NIH RePORTER tool, a repository of information about NIH-funded research projects, and show you how to find information that may be useful to know before you start writing a grant application. A future Feedback Loop post will cover the thesaurus-based search tool called Like This.

Main Query Form

From RePORTER's Main Query Form, you can search by principal investigator name, project number, organization, text term(s) and many other criteria.

If you want to know which NIH institutes or centers fund projects like yours, or which study section would be most appropriate to review your application, then searching by text term(s) would probably be the best approach.
Grants: A to Z

http://grants.nih.gov/grants/oer.htm
Get the Team Organized!
Plan Ahead… Seriously!
TWO ROADS DIVERGED IN A WOOD, AND I—I TOOK THE ONE LESS TRAVELED BY, AND THAT HAS MADE ALL THE DIFFERENCE.

- ROBERT FROST

R21 ($275K spread over 2 yrs, non-renewable)
- High(er) risk and reward
- Little/no supporting data

R03 (2 yrs, $50K per year, non-renewal)
- Little/no supporting data
- succinct task(s)

R01 (4-5 yrs, $250 - 400K+, renewable, a “real” grant)
- Convincing preliminary data for each aim
- Longer term questions
- Multiple complexities
Targeting IC Priorities: an example

**NIBIB mission**
accelerating the application of biomedical technologies…[via]integrating the physical and engineering sciences with the life sciences to advance basic research and medical care.

**NINDS mission**
seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease.

---

**Novel polymer scaffold for tissue regeneration**

**Neural progenitor cells in biomimetic matrix in rat brain**

**Pivotal large animal studies for stroke therapy**

---

**Neural differentiation of stem cells**

**Imaging cells transplanted to the brain**
• Read the IC Mission Statement
• Better yet: contact the Program Director!
Research Training and Career Awards

- **Training Grants** – $T$
  - Institutional
  - Predoctoral and Postdoctoral

- **Fellowships** – $F$
  - Individual
    - Predoctoral – F31
    - Postdoctoral – F32

- **Career Development Awards** – $K$
Elements of the Grant Application

- Specific Aims: your key to success
- Research Strategy: helpful hints
- Other Considerations
- Funding Emerging Science, Technology Development
Planning Meeting Output: Blueprint for Successful Research

Project Title: *really a quick summary*

Principal Investigator(s) and Key Personnel: *defines role, commitment*

Overall goal: *resolve an important issue in a timely manner*

Specific goal: *best stated as a hypothesis (a boastful claim, substantiated by data)*

Impact: *2-3 sentences, define success, distill innovation and significance*

**RESEARCH Responsibilities, Costs, Milestones and Timeline**

<table>
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<tr>
<th>Overseer</th>
<th>Cost</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Q5</th>
<th>Q6</th>
<th>Q7</th>
<th>Q8</th>
</tr>
</thead>
</table>

1. Validate the ... *(THIS AIM MUST WORK—i.e. no/low risk here!)*
   1a. Compare... confirm...
   1b. Optimize the dose/time course...

2. Elucidate the mechanism... *(May omit for high risk (e.g. R21) grants.)*
   2a. 
   2b. 
   2c. 

3. Assess the biocompatibility of ... in a ... *(Transition to next grant.)*

* High-risk element. Propose and discuss alternatives. Decision point.
Structuring Your Grant Application

- Strong Research Question
- Medical Need = outcomes (low hanging fruit)
- Aim 1: preliminary data
- Aim 2: approach background
- Aim 3: approach background (preliminary data)
Your Grant Application should reflect your best thinking.
NIH Applications

Key Elements
- Cover Letter and Title Pages
- Abstract (1 page synopsis)
- Budget with Justifications
- Biosketches of Investigators
- Resources and Facilities
- Specific Aims (1 page)
- Research Strategy (6 or 12 pages)
  - Significance
  - Innovation
  - Approach
    - Preliminary Studies/Progress Report
    - Experimental Design and Methods
- Bibliography and References
- Resource Authentication Appendix
  - Human Subjects
  - Other (animals, consortium, multi-PI, select agents, other support, resource sharing)
- Commercialization Plan (Phase II SBIR/STTR only!)

Review Criteria
- Significance
- Investigator(s)
- Innovation
- Approach
- Environment
- Human/Animal Studies
- Commercialization Plan Quality (SBIR/STTR Phase II)
SPECIFIC AIMS:
What do you intend to do?

- Single and most important page of application
- Introductory paragraph should
  - Capture the vision with a broad goal justifying the research question
  - Describe your unique and innovative solution
  - Engage the reader with
    - strong, solid, testable hypotheses, or
    - discrete, finite technology development goal
  - Summarize relevance and feasibility of the approach(es)
- Succinctly state each research objective in a topic phrase or sentence
  - Aims independent yet related to overall goal
  - Add sub-aims as needed: experiments support aims, aims test hypotheses
  - Avoid dense text and acronym overload
- End with impact: define success and point to the future
Conversation at the Study Section’s Mid-Morning Break

Me: I think I have this figured out. You guys have pretty much decided on an impact score by the time you finish reading the Specific Aims page, right?

Reviewer #1 (hesitantly): Well... yes, that’s right.

Me: And the rest is filling in the details, looking for confirmation of your opinion, scanning for fatal flaws...

Reviewer #2: That about sums it up, yes.
Tell your story in five compelling, concise, plain-language paragraphs!

1. **Outline an important medical problem and your timely, innovative solution.** Describe the big picture quantitatively. How can science/engineering help? Does this push the edge of the possible in a new way?

2. **Define the challenge for this application.** What is your specific target and hypothesis? How will you get there? How do you know?

3. **State each of your (three) Specific Aims in a single sentence in bold face.** Then, identify strategies, methods, assays to be used, and data expected.

4. **Overview the competencies of the team and the resources.** Why is this the right group at the right place and time? Outline your specific skill sets.

5. **What happens when you succeed? What are the next steps?** How will paradigms shift or treatment change, and what will this project contribute?

**Significance – Innovation – Investigator(s) – Approach – Environment**
Research Strategy - A Deeper Dive

- Significance (10% of available space)
- Innovation (5% of available space)
- Approach
  - Preliminary Studies/Progress Report
  - Experimental Design and Methods
Significance is About CONTEXT

- Reviewers will not hunt for the value in your application
- Stand out in your ideas and execution plans, not in your presentation style
- Do your homework and know your audience: find and target the best Study Section
Novelty Can Be Difficult to Define

- Innovative aspects must be obvious
- Succinct analysis of the literature is key
- Moving from Invention to Innovation is a good strategy: balance feasibility with bold research

Inspiration → Invention → Innovation
RESEARCH STRATEGY – Approach: Prior Work: What has already been done?

- Data must lead to the current proposal, supporting the feasibility of the proposed work
- Demonstrate that the investigator has:
  - mastery of (and/or access to) the required techniques
  - ability to manage and work with collaborators/partners
  - sufficient attention to important details (i.e. accurate, carefully assembled figures, tables, graphs)
- Reviewers will NOT look anything up!
  Provide sufficient, relevant details for an informed judgment
RESEARCH STRATEGY - Approach: Methods: How will it be done?

- Do tasks relate to the Specific Aims?
  - Provide an overview and conceptual framework. Connect all the dots.

- Are the experiments logical, grounded, and well-integrated?
  - Why are the proposed methods the best way to go? Be sure this study is not “a technology looking for a problem”
  - Less detail needed for established techniques
  - Alternatives for high risk elements add to the feasibility
  - Biohazards identified here, then fully discussed in a subsequent section

- Are end-points/milestones clearly defined, with appropriate benchmarks? Is there a sensible timeline?

- Is the appropriate statistical analysis included?
Be OUTSTANDING in your field…

- Cite relevant data, especially yours!
- Integrate observations from other fields: be disruptive BUT…
- Connect the dots
- Propose alternatives for the riskier aspects

... not OUT STANDING in your field.

- Avoid jargon and uncommon usage
- Repeat and reinforce concepts, not language
- Follow the format
- Be concise yet clear

... improving health by leading the development and accelerating the application of biomedical technologies
## Enhancing Reproducibility: Rigor and Transparency in Research Grants

<table>
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<tr>
<th>Element</th>
<th>Definition</th>
<th>Placement in Application</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scientific Premise</strong></td>
<td>Key data justifying project</td>
<td>Significance</td>
<td>Exploratory science may need more explanation</td>
</tr>
<tr>
<td><strong>Scientific Rigor</strong></td>
<td>Robust, unbiased experimental design, methodology, analysis, interpretation, results reporting</td>
<td>Approach</td>
<td>Transparency establishes firm research foundation, supports innovation</td>
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<tr>
<td><strong>Relevant Biological Variables</strong></td>
<td>Critical factors affecting health or disease (e.g. sex, age, source, weight, genetic strain)</td>
<td>Approach</td>
<td>Consideration of sex <strong>required</strong> for human/animal studies</td>
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<tr>
<td><strong>Key Resource Authentication</strong></td>
<td>Integral components with inherent variability or unique characteristics (e.g. cell lines, biologics, speciality chemicals)</td>
<td>Attach plan (single page) as appendix</td>
<td>Not factored into scoring, but required prior to funding</td>
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Human and Animal Subjects

Important considerations in overall application scoring (feasibility of the work) and as pre-award administrative issues.

✓ Safeguarding the rights and welfare of individuals as subjects in research based on DHHS regulations and established, internationally recognized ethical principles.

✓ Grantees are responsible for the humane care and treatment of animals under NIH-supported activities.

www.hhs.gov/ohrp

grants.nih.gov/grants/olaw

... improving health by leading the development and accelerating the application of biomedical technologies
Biosketches

- Required for all investigators
  - Each participant in a Multiple-PI application must show complementary and integrated expertise
- List degrees chronologically
- A. Personal statement: your experience, qualifications needed for this project, with up to four publications as evidence
- B. List positions, honors, concluding with current position
- C. Contributions to Science
  - Brief description of five areas: historical background, findings and impact
  - May include up to four publications (or other data, e.g. patents) as evidence
  - Include a link to complete publication list in PubMed
- D. Research Support: overview, distinguish from proposed
  - Ongoing and completed projects over past three years
  - Listed by relevance to the proposed work

Resources and Facilities

Identify and justify

- **Facilities**
  - Laboratory and offices, clinical sites, animal housing/handling, machine/electronics shops - if applicable

- **Multiple performance sites, as applicable**

- **Equipment** (especially if unusual)

- **How the environment will contribute to success**
  - institutional support, intellectual rapport, access to subject populations

- **For Early Stage Investigators: institutional investment in your success**
  - classes, training, collegial support, mentorship programs, logistical support, protected time for research with salary support, etc.

- **Handling of biohazards**
  - Consider safety of research personnel and/or environment

... improving health by leading the development and accelerating the application of biomedical technologies
Budgetary Issues

Developing Your Budget

On This Page:
- Cost Considerations
- Budgets: Getting Started
- Allowable direct vs. allowable F&A costs
- Modular vs. Detailed Budgets
- Modular Budgets
- Detailed Budget: Personnel (Sec A & B)
- Detailed Budget: Equipment, Travel, and Trainee Costs (Sec C, D, and E)
- Detailed Budget: Other Direct Costs (Sec F)
- Consortiums/Subawards
- Understanding the Out Years
- Other resources

As you begin to develop a budget for your research grant application and put all of the relevant costs down on paper, many questions may arise. Your best resources for answering these questions are the grants or sponsored programs office within your own institution, your departmental administrative officials, and your peers. They can answer questions such as:

- What should be considered a direct cost or indirect cost?
- What is the fringe benefit rate?
- What is the graduate student stipend rate?
- What Facilities and Administrative (F&A) costs rate should I use?

Below are some additional tips and reminders we have found to be helpful for preparing a research grant.

http://grants.nih.gov/grants/developing_budget.htm
Getting Funded in an Emerging Field

NIH funds **high risk/high reward** research if there is

- Potential for high impact
- Novel approach, not necessarily a new idea (a fundamental publication builds credibility)
- Deep expertise in the general area on the team (confidence in capability is key)
- A compelling research plan—anticipate obstacles and propose alternatives
- **BONUS POINTS:** reviewer familiarity with the basics

... improving health by leading the development and accelerating the application of biomedical technologies
"Simple can be harder than complex. You have to work hard to get your thinking clean to make it simple. But it's worth it in the end, because once you get there, you can move mountains."

“Everything should be made as simple as possible, but not simpler.”
NIH Grant Application?

Read your completed draft with a reviewers eye!

- “Significance”
- Actual Significance
- Axe Grinding
- Quality Science
- “Translation”
- Actual Translation
- Bragging
- Handwaving
- Begging for Spare Change

Realistically revise.

... improving health by leading the development and accelerating the application of biomedical technologies
Do I Contact NIH *Before* Applying?

**Mandatory:**

- Application with budget >$500,000 direct costs for any single year
- R13 Conference Grants

**Optional:**

- When RFA’s request a Letter of Intent

**Recommended:**

- When you think about applying for *any* grant
The Application is Complete...You’re Done!

Well, actually, now you are ready to start the submission process.

- Grants.gov is the portal for NIH applications
- eRA Commons is the doorway to the NIH system
Just Send it
Submit Through grants.gov...

Key Take-Aways:

• Only the Authorized Organizational Representative (AOR) has the authority to submit applications.

• You are responsible for verifying that the application is viewable in the eRA Commons. If you cannot view the application in the Commons, we can’t review it.

• You must correct all errors before the eRA system will assemble an application image.

• If you experience a system issue that you believe threatens your ability to submit on time, carefully follow these guidelines to document your problems and continue working to resolve your issues.
Now It’s Our Turn: The Review Process

- Find the Best Review Committee
- Understand the Assessment
- Responding to the Evaluation
Receipt and Referral, Center for Scientific Review (CSR) to an NIH Institute (IC)

Electronic SF424 R&R submitted through grant.gov and the eRA Commons

Error free, warnings addressed

CSR Referral Office assigns the application...

Application assessed for completeness & eligibility

Notice of assignment available in eRA Commons in 4 weeks.

to an NIH Institute (IC)

to Integrated Review Group (IRG) and then a study section (SRG)

Check your eRA Commons account for updates!
Decoding Your NIH Grant Number

1 = new
2 = renewal
3 = supplement
4 = administrative extension (e.g. MERIT, FastTrack)
5 = non-competing continuation
7 = Change of Grantee Institution
9 = Change of NIH Institute or Center

1 = new
2 = renewal
3 = supplement
4 = administrative extension (e.g. MERIT, FastTrack)
5 = non-competing continuation
7 = Change of Grantee Institution
9 = Change of NIH Institute or Center

Application Type
Activity Code
Institute Code
Serial Number
Support Year
Extension

1
R01
EB
12345
01
A1

AA = NIAAA
AG = NIA
AI = NIAID
AR = NIAMS
AT = NCCAM
CA = NCI
DA = NIDA
DC = NIDCD
DE = NIDCR
DK = NIDDK
EB = NIBIB
ES = NIEHS
EY = NEI
GM = NIGMS
HD = NICHD
HG = NHGRI
HL = NHLBI
LM = NLM
MD = NIMHD
MH = NIMH
NR = NINR
NS = NINDS
TR = NCATS
TW = FIC

A1 = resubmission
S1 = supplement
What happens to your grant application?

NIH Peer Review?

Your proposals?
It’s an orderly universe.

Your application is reviewed by either ... 

- Chartered (Standing) Scientific Review Group (SRG), or “Study Section”
- Special Emphasis Panel (SEP)
  - organized by the Center for Scientific Review (CSR)
    - Conflicts on the panel (e.g. reviewer is a PI on the grant application)
    - Special review for a unique solicitation (e.g. PAR)
  - convened within a home IC of a highly specific initiative (e.g. RFA)
Peer Review and You

Peer Review Policies & Practices

Overview of Peer Review Process

- This page provides detailed information about Peer Review Policies and Practices. For an overview of general information about Peer Review, visit Peer Review Process.

What's New in Peer Review

- NOT-OD-11-101 Resubmission of Applications with Pending Appeals of NIH Initial Peer Review
- NOT-OD-11-064 Appeals of NIH Initial Peer Review
- NOT-OD-11-047 Notice of Change in Policy on the Submission of Reference Forms for Kirschstein-NRSA Fellowships
- NOT-OD-11-035 NIH Policy on Late Submission of Grant Applications
- NOT-OD-11-023 Reminder of Policies Affecting Submission of NIH Grant Applications

Related Resources

- NIH Peer Review Policies and Practices (NIH Staff Only)
- Rosters of NIH Scientific Review Groups
- Office of Federal Advisory Committee Policy
- Enhancing Peer Review
- Peer Review Advisory Council (PRAC)
- Peer Review Notes

http://grants.nih.gov/grants/peer/peer.htm
Your application may be REVIEWED by one of:

Bioengineering Sciences and Technology (BST)
BDMA, BMBI, GDD, ISD, MABS, NANO

Healthcare Delivery and Methodologies (HDM)
BCHI, BMRD, CIHB, CLHB, DIRH, HDEP, HSOD, NRCS

Cell Biology (CB)
BVS, NCSD, CMAD, CSR, DEV1/2, ICI, MBPP, MIST

Endocrinology, Metabolism, Nutrition and Reproductive Systems (EMNR)
MCE, ICER, CMIR, PN, CADO, IPOD, CISO, INMP, F06

Immunology (IMM)
CMIA/B, IAI, IHD, III, IMM-M, TTT, VMD, F07

Interdisciplinary Medical Sciences and Training (IMST)
EBIT, various training

Emerging Technologies and Training in Neuroscience (ETTN)
MNG, BNVT, NOIT, F01/2/3

Vascular and Hematology (VH)
AICS, ELB, HM, HP, MCH, VCMB, F10B

Biology of Development and Aging (BDA)
International/Cooperative Projects

Behavior and Behavioral Processes (BBBP)
APDA, BRLE, CP, CPDD, LCOM, MESH, MFSR

Infectious Diseases and Microbiology (IDM)
BACP, CRFS, DDR, HIBP, PTHE, VB, VIRAB, F13

Risk Prevention and Health Behavior (RPHB)
BMIO, PDRP, PRDP, RPIA, SPIP, F16

Digestive, Kidney and Urological Systems (DKUS)
CIMG, GMPB, HBPP, KMBD, PBKD, UGPP, XNDA

Population Science and Epidemiology (PSE)
BGES, CASE, EPIC, IRAP, KNOD, NAME, SSPA/B

Cardiovascular and Respiratory Sciences (CVRS)
CCHF, CDD, CICS, ESTA, LCMI, LIRR, MIM, RIBT, F10A

Integrative, Functional and Cognitive Neuroscience (IFCN)
AUD, LAM, NAL, NMB, NNRS, SCS, SMI, SPC

Molecular, Cellular and Developmental Neuroscience (MDCN)
BPNS, CMBG, CMND, DDNS, MNPS, NCF, NDPR, NOMD, NTRC, SYN

Brain Disorders and Clinical Neuroscience (BDCN)
ANIE, ASG, BINP, CDIN, CNBT, CNN, CNNT, DBD, DPVS, NPAS, PMDA

Biological Chemistry and Molecular Biophysics (BCMB)
BBM, MSFA/B/D/C/D, SBCA/B

Risk Prevention and Health Behavior (RPHB)
BMIO, PDRP, PRDP, RPIA, SPIP, F16

Genes, Genomes and Genetics (GGG)
MGA/B, GCAT, GVE, GHD, PCMB, TAG

Oncology 1 – Basic Translational (OBT)
CAMP, CE, CG, MONC, TCB, TME, TPM

Oncology 2 – Translational and Clinical (OTC)
BMCT, CBSS, CDP, CII, CONC, DMP, DT, RTB

Infectious Diseases and Microbiology (IDM)
BACP, CRFS, DDR, HIBP, PTHE, VB, VIRAB, F13

>200 Standing Scientific Review Groups (SRGs or Study Sections) housed in 25 Integrated Review Groups at CSR
How to Identify the Best Study Section

Integral Review Groups (IRGs)

Review activities of the Center for Scientific Review (CSR) are organized into Integrated Review Groups (IRGs). Each IRG represents a cluster of study sections around a general scientific area. Applications generally are assigned first to an IRG, and then to a specific study section within that IRG for evaluation of scientific merit.

http://public.csr.nih.gov/StudySections/Pages/default.aspx
Bioengineering Sciences and Technologies IRG [BST]
Bioengineering Sciences and Technologies IRG [BST]

The Bioengineering Sciences and Technologies [BST] IRG reviews grant applications that focus on fundamental aspects of bioengineering and technology development in the following areas: gene and drug delivery systems, imaging principles for molecules and cells, modeling of biological systems, bioinformatics and computer science, statistics and data management, instrumentation, chips and microarrays, biosensors, and biomaterials. Biological context is important in bioengineering, and a central premise in organization of this IRG is the need for effective review of bioengineering and technology development in early stages before specific practical uses are proven.

Study Sections

» Biodata Management and Analysis Study Section [BDMA]
» Biomaterials and Biointerfaces Study Section [BMBI]
» Gene and Drug Delivery Systems Study Section [GDD]
» Instrumentation and Systems Development Study Section [ISD]
» Modeling and Analysis of Biological Systems Study Section [MABS]
» Nanotechnology Study Section [NANO]

Applications

Research grants (R01, R21, R15, etc.), Program Project and Center Grants (P01, P41 etc.), and Cooperative Agreements (U01, U54 etc.) are reviewed in the BST IRG.
Review Group Description: What is the science focus?

Science Focus of “nearest neighbor” study sections
Cover Letters Help Target Your Review

Applicants can suggest

- Review Group assignment
- Expertise necessary for a full and fair review
- Primary (and secondary) Institute or Center (IC) assignment
- Reviewers with potential conflicts
- Do not suggest possible reviewers, they will be disqualified.

Other Important Information

- Reasons for a late submission
- Note eligibility for continuous submission
- Highlight this application as one of a set, if applicable
- Acknowledge NIH approval for acceptance of
  - A budget >$500K/yr
  - Conference grant

Suggested format and other information at

http://cms.csr.nih.gov/ResourcesforApplicants/CoverLet.htm
# NIH Scoring System

<table>
<thead>
<tr>
<th>Impact</th>
<th>Full Description</th>
<th>Score</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Exceptionally strong with essentially no weaknesses</td>
<td>1</td>
<td>Exceptional</td>
</tr>
<tr>
<td></td>
<td>Extremely strong with negligible weaknesses</td>
<td>2</td>
<td>Outstanding</td>
</tr>
<tr>
<td></td>
<td>Very strong with only some minor weaknesses</td>
<td>3</td>
<td>Excellent</td>
</tr>
<tr>
<td>Medium</td>
<td>Strong but with numerous minor weaknesses</td>
<td>4</td>
<td>Very Good</td>
</tr>
<tr>
<td></td>
<td>Strong but with at least one moderate weakness</td>
<td>5</td>
<td>Good</td>
</tr>
<tr>
<td></td>
<td>Some strengths but also some moderate weaknesses</td>
<td>6</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>Low</td>
<td>Some strength but with at least one major weaknesses</td>
<td>7</td>
<td>Fair</td>
</tr>
<tr>
<td></td>
<td>A few strengths and a few major weaknesses</td>
<td>8</td>
<td>Marginal</td>
</tr>
<tr>
<td></td>
<td>Very few strengths and numerous major weaknesses</td>
<td>9</td>
<td>Poor</td>
</tr>
</tbody>
</table>

**Minor weakness:** Easily addressable weakness that does not substantially lessen impact.

**Moderate Weakness:** Impact lessened.

**Major Weakness:** Impact severely limited.

**Overall impact score:** = panel average x 10. Most scores are then percentiled for comparison across review groups.
What Goes Into the Impact Score?

Evaluation Criteria

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

Each gets a score. The overall Impact Score is NOT AN AVERAGE OF THESE, because reviewers rate criteria differently.

Other Elements Affecting Score

- Human/Animal Subjects Protections
- Biohazards

Administrative Concerns (not scorable)

- Time and Budget
- Commitment/Technical Overlap
- Resource Sharing
- Other?
Why Percentiles?

Discrimination by score favors Study Section #1

Discrimination by percentile shows no favor
NIH’s Review System for Grants

Scientific Review Group (SRG)
- Independent outside review
- Evaluate scientific merit, significance
- Recommend length and level of funding

Scientific Review Group (SRG) Output: Priority Score and Summary Statement

Advisory Council
- assess quality of SRG process
- offers recommendation to Institute Staff
- evaluates program priorities and relevance
- advises on policy

Advisory Council Output: Funding Recommendations

Institute Director
- makes final decision based on Council input, programmatic priorities
- Must also Pass Administrative Review

Institute Director Output: Awards or Resubmission
Who Makes Actual Funding Decisions?

The Institute Director!

Factors Considered:

- Scientific Merit
- Contribution to Institute Mission
- Program Balance
- Availability of Funds
Close, but no cigar?

You get one more try.

- Revise and Resubmit
- It’s not personal
- Absorb the critiques
  - make suggested changes
  - provide additional justification for your original approach
- Explain the changes in a one page “Introduction”
If at first you don’t succeed, redefine SUCCESS
The Program Official can help you plow new ground.
Common Problems

- **Low/No significance**
  - Unimportant problem limits significance
  - Unconvincing case limits impact; feasibility questionable
  - Irrelevant, inconsistent, or insufficient reference to published work

- **Weak PI/Research team:** Insufficient experience with essential methodologies

- **Lack of innovation:** evolutionary not revolutionary

- **Questionable reasoning in experimental approach**
  - Errors in design = FATAL FLAW
  - Failure to consider potential pitfalls and alternatives

- **Diffuse, superficial, or unfocused research plan**
  - Lack of critical experimental detail
  - Unrealistically large amount of work proposed
  - No clear milestones, decision points

- **Poor environment:** weakly documented institutional support

- **Serious/unresolvable human/animal subjects or biohazard concerns**

See also: [http://www.principalinvestigators.org/article.php](http://www.principalinvestigators.org/article.php)
Do science because you can’t imagine doing anything else, and enjoy the ride. No one said it would be easy, only wild.

- Doug Green
Are you ready to run with the big dogs?

Rosemarie Hunziker, PhD

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National Institute of Biomedical Imaging and Bioengineering (NIBIB)
National Institutes of Health (NIH)

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