

Winning NIH Grants: Swimming with Sharks



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and Biomaterials

NIBIB/NIH

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TODAY'S AGENDA: THE DEEP DIVE INTO NIH GRANTS

- **Plan Ahead, Get Prepared**
 - 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
 - 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

- Get Help from the Inside
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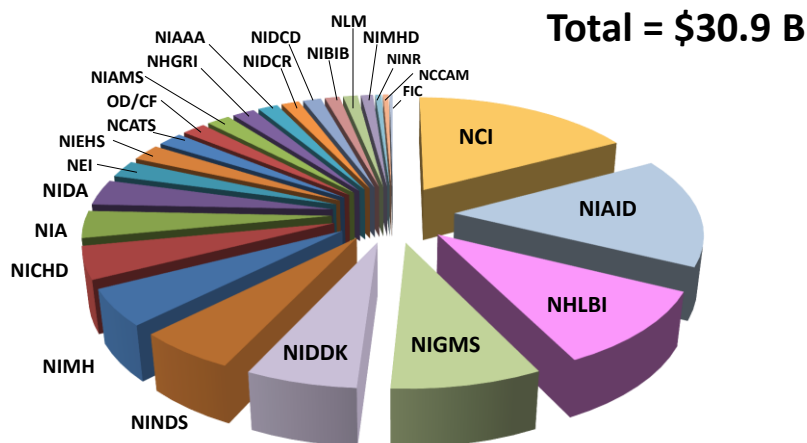


... improving health by leading the development and accelerating the application of biomedical technologies



NIH FY12 Budget

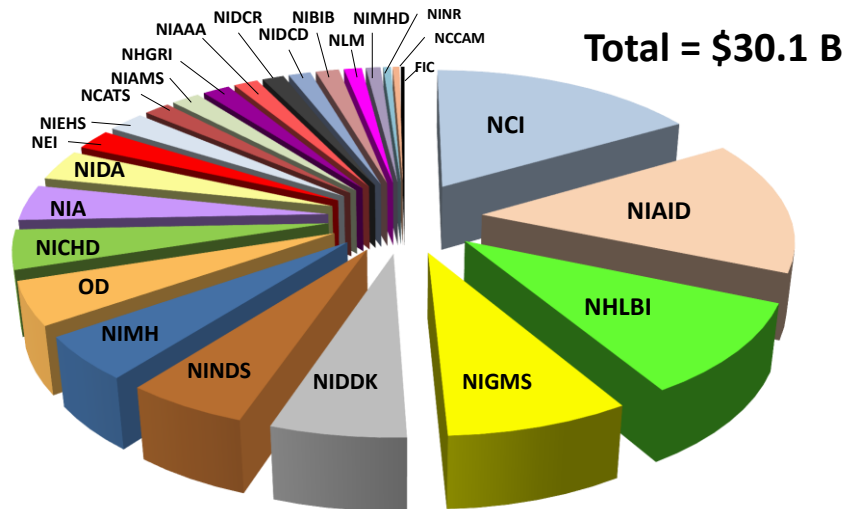
NIH Divides most of its investment according to the interests of the component parts (i.e. Institutes or Centers), with <4% allocated to trans-NIH initiatives.



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

NIH FY14 Budget

NIH Divides most of its investment according to the interests of the component parts (i.e. Institutes or Centers), with <4% allocated to trans-NIH initiatives.



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

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



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NIH Institute/Center Web Sites

U.S. Department of Health & Human Services

NIH National Institutes of Health
Turning Discovery Into Health

Search

For Employees | Staff Directory | En Español

Health Information | Grants & Funding | News & Events | Research & Training | **Institutes at NIH** | About NIH

NIH Home

INSTITUTES, CENTERS & OFFICES

NIH is made up of **27 Institutes and Centers**, each with a specific research agenda, often focusing on particular diseases or body systems. **NIH leadership** plays an active role in shaping the agency's activities and outlook. [Learn more about NIH](#) ▶

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.

Quick Links

NCI	NIAMS	NIEHS	CIT
NEI	NIBIB	NIGMS	CSR
NHLBI	NICHD	NIWH	FIC
NIHGRI	NIDCD	NIHHD	NCCAM
NIA	NIDCR	NINDS	NCATS
NIAAA	NIDDK	NINR	CC
NIAD	NIDA	NLM	OD

www.nih.gov/icd/

**Each NIH Institute/
Center has a HOME PAGE**

NIBIB National Institute of Biomedical Imaging and Bioengineering
National Institutes of Health
ENGINEERING & IMAGING FOR THE FUTURE

En Español | Quick Links

HOME ABOUT NIBIB **RESEARCH** FUNDING TRAINING & CAREERS NEWS & EVENTS

CTC Microchip: A One-in-a-Billion Technology
With enough sensitivity to detect and trap a single at-large cancer cell from among a billion blood cells, the impressive new Circulating Tumor Cell (CTC) microchip is showing much promise as it points the way to a new era in the fight against cancer.

Learn More

Technology Focus Health Information Multimedia Gallery Science Education Research News

Model: <http://www.xxxxx.nih.gov>
<http://www.nibib.nih.gov/>

NIBIB National Institute of Biomedical Imaging and Bioengineering
National Institutes of Health
ENGINEERING & IMAGING FOR THE FUTURE

En Español | Quick Links

HOME ABOUT NIBIB **RESEARCH** FUNDING TRAINING & CAREERS NEWS & EV

Research

- Labs At NIBIB (Intramural)
- Scientific Program Areas (Extramural)
- Biotechnology Resource Centers
- Quantum Grants
- Resources for Researchers

SIGN UP FOR OUR LISTSERV

Home > Research > Scientific Program Areas (Extramural) > **Biomaterials Program Area**

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 us 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 c these materials and their clinical performance.

Relevant Study Sections

Biomaterials and Biointerfaces (BMBI)

Does NIH Already Support My Interest Area?

U.S. Department of Health & Human Services

NIH Research Portfolio Online Reporting Tools (RePORTER)

Search

HOME | ABOUT RePORTER | FAQs | GLOSSARY | CONTACT US

QUICK LINKS | RESEARCH | ORGANIZATIONS | WORKFORCE | FUNDING | REPORTS | LINKS & DATA

QUICK LINKS

Home > Quick Links

RePORTER

The Report Expenditures and Results tool allows users to search a repository of NIH-funded research projects and access publications and patents resulting from NIH funding.

[More Details](#)

NIH Data Book

The NIH Data Book (NDB) provides basic summary statistics on extramural grants and contract awards, grant applications, the organizations that NIH supports, the trainees and fellows supported through NIH programs, and the national biomedical workforce.

[More Details](#)

Report Catalog

The Report Catalog is a menu driven interface geared for the NIH familiar user to provide customized reporting. A graphic depiction of some major funding mechanisms, and activity codes gives a hierarchical view of project organization.

[More Details](#)

Success Rates

Computed on a FY basis, success rates

Funding Facts

Quick access to statistics from the NIH

The Research, Condition, and Disease Categorization

<http://report.nih.gov/quicklinks.aspx>

NIH Searchable Databases Contain Abstracts of All Funded Projects

U.S. Department of Health & Human Services

NIH Research Portfolio Online Reporting Tools (RePORTER)

QUICK LINKS | RESEARCH | ORGANIZATIONS | WORKFORCE

Home > RePORTER > Query Form

NIH RePORTER
Version: 5.4.0
04/11/2013 Release Note: New enhancements now available. View Release Notes for more information.

QUERY | BROWSE NIH

SUBMIT QUERY | CLEAR QUERY

NIH (non) ARRA Selection: [] SELECT

Text Search (Logic): []

And Or Advanced

Search in:

- Projects
- Publications
- Project Title
- Project Terms
- Project Abstracts

Limit Publication search to

Start Year: 2012 End Year: 2013

Project Number: []
Format: SRU1CA012345-04
Use % for wildcard, e.g. %R21%
Enter multiple project numbers

Activity Code: [] SELECT

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. [Show/Hide Search Criteria](#)

Click on the column header to sort the results

T: Application Type; Act: Activity Code; Project: Admin IC, Serial No.; Year: Support Year/Supplement/Amendment

T	Act	Project	Year	Sub #	Project Title	Contact PI / Project Leader	Organization	FY	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects
1	R01	CA166111	01A1		TUMOR ANTIGEN-SPECIFIC T-CELLS AND HEPATOCELLULAR CARCINOMA	KAPLAN, DAVID E	UNIVERSITY OF PENNSYLVANIA	2013	NCI	NCI	\$249,000	
5	R01	AR055993	03		TISSUE REGENERATION BY BIOPHYSICAL SIGNALING	KAPLAN, DAVID L et al.	TUFTS UNIVERSITY MEDFORD	2012	NIAMS	NIAMS	\$323,395	
5	R01	AR061988	02		ELECTROTHERAPEUTIC STRATEGIES FOR CONNECTIVE TISSUE REPAIR	KAPLAN, DAVID L et al.	TUFTS UNIVERSITY MEDFORD	2012	NIAMS	NIAMS	\$645,728	
3	P41	EB002520	09S1		TISSUE ENGINEERING RESOURCE CENTER	KAPLAN, DAVID L	TUFTS UNIVERSITY MEDFORD	2013	NIBIB	NIBIB	\$40,625	
5	P41	EB002520	09		TISSUE ENGINEERING RESOURCE CENTER	KAPLAN, DAVID L	TUFTS UNIVERSITY MEDFORD	2012	NIBIB	NIBIB	\$1,152,600	
5	R01	EB011620	02		BIOMATERIAL APPLICATIONS OF RECOMBINANT BACTERIAL COLLAGENS	KAPLAN, DAVID L et al.	TUFTS UNIVERSITY MEDFORD	2012	NIBIB	NIBIB	\$324,245	
1	R01	EB014283	01A1		MULTIFUNCTIONAL TROPOELASTIN-SILK BIOMATERIAL SYSTEMS	KAPLAN, DAVID L	TUFTS UNIVERSITY MEDFORD	2012	NIBIB	NIBIB	\$305,288	
1	U01	EB014976	01		MODELS TO PREDICT PROTEIN BIOMATERIAL PERFORMANCE	KAPLAN, DAVID L et al.	TUFTS UNIVERSITY MEDFORD	2012	NIBIB	NIBIB	\$646,995	
1	R01	EB016041	01		IN VITRO BIOREACTOR SYS FOR PLATELET FORMATION	KAPLAN, DAVID L	TUFTS UNIVERSITY MEDFORD	2012	NIBIB	NIBIB	\$337,137	
5	R01	EY020856	03		TISSUE ENGINEERING CORNEA REPLACEMENTS	KAPLAN, DAVID L	TUFTS UNIVERSITY MEDFORD	2012	NEI	NEI	\$369,557	

Click for Abstract

... of Useful Information.

QUICK LINKS RESEARCH ORGANIZATIONS WORKFORCE FUNDING REPORTS LINKS & DATA

Home > RePORTER > Project Information MyRePORTER Login | Register System Health: GREEN

Project Information

5R01EB014283-02 Back to Query Form Back to Search Results Print Version

PREVIOUS Project 9 of 12 NEXT

DESCRIPTION	DETAILS	RESULTS	HISTORY	SUBPROJECTS	SIMILAR PROJECTS	NEARBY PROJECTS	LINKS	NEWS AND MORE
Project Number: 5R01EB014283-02 Title: MULTIFUNCTIONAL TROPOELASTIN-SILK BIOMATERIAL SYSTEMS Contact PI / Project Leader: KAPLAN, DAVID L Awardee Organization: TUFTS UNIVERSITY MEDFORD		Program Official Information: Name: HUNZIKER, ROSEMARIE Email: Click to view PO email address						
Contact PI / Project Leader Information: Name: KAPLAN, DAVID L Email: Click to view Contact PI / Project Leader email address Title:		Other PI Information: Profile Exists No Profile						
Organization: TUFTS UNIVERSITY MEDFORD Name: TUFTS UNIVERSITY MEDFORD City: MEDFORD Country: UNITED STATES (US)		Department/ Organization Type: ENGINEERING (ALL TYPES) BIOMED ENGR/COL ENGR/ENGR STA		Congressional District: State Code: MA District: 07				
Other Information: FOA: EA-11-260 Study Section: Gene and Drug Delivery Systems Study Section (GDD) Fiscal Year: 2013 Award Notice Date: 25-JUL-2013		DUNS Number: 073134835 Project Start Date: 1-AUG-2012 Budget Start Date: 1-AUG-2013		CFDA Code: 286 Project End Date: 31-JUL-2016 Budget End Date: 31-JUL-2014				

Local intranet | Protected Mode: Off

NIGMS Feedback Loop Blog

A catalyst for interaction with the scientific community



NIGMS Feedback Loop Blog- A catalyst for interaction with the scientific community

How to Use RePORTER When Preparing New Grant Applications



Posted by **James Onken** on **Monday, Dec 3, 2012 1:58 PM EST**
[Post a Comment](#) | [View Comments \(0\)](#)

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.



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- > [Other Policies](#)
- > [NIGMS Web Site](#)
- > [NIGMS Funding Announcements](#)

<https://loop.nigms.nih.gov/index.php/2012/12/03/how-to-use-reporter-when-preparing-new-grant-applications/>

Grants: A to Z

U.S. Department of Health & Human Services www.hhs.gov



Office of Extramural Research
National Institutes of Health



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Search:

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Forms & Deadlines
Grants Policy
News & Events
About OER
NIH Home

Grants Process

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- [Grants Process Overview](#)
- [Types of Grant Programs](#)
- [How to Apply](#)
- [Peer Review Process](#)
- [Award Management](#)
- [Foreign Grants Information](#)
- [NIH Financial Operations](#)

Electronic Grants

- [Electronic Research Administration \(eRA\)](#)
- [eRA Commons](#)
- [Applying Electronically](#)

Global OER Resources

- [Glossary & Acronyms](#)

About Grants

Grant Application Basics

- [What Does NIH Look For?](#)
- [Who Is Eligible for an NIH Grant?](#)
- [Finding a Funding Opportunity](#)

How to Apply

- [Submitting Your Application](#)
- [NIH Forms and Applications](#)
- [Receipt Dates and Deadlines](#)
- [Grants Process Overview](#)
- [Tracking Your Application](#)

Types of Grant Programs

- [Search](#)
- [Research Grants](#)
- [Program Project/Center Grants \(P series\)](#)
- [Resource Grants](#)
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Grants Process Overview

- [Grants Process At-A-Glance \(Graphic\)](#)
- [Planning Your Application](#)
- [Writing Your Application](#)
- [Developing Your Budget](#)
- [How to Apply](#)

Award Management

- [Overview](#)
- [Pre-Award Process - Competing Applications](#)
- [Pre-Award Process - Non-Competing Awards](#)
- [Award Process](#)

NIH Financial Operations

- [Introduction](#)
- [General Resources](#)
- [Resources for FY 2010](#)
- [Resources for FY 2009](#)
- [FY 2010 Funding Strategies](#)

http://grants.nih.gov/grants/about_grants.htm

Get the Team Organized!



**Plan Ahead...
Seriously!**

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

	Overseer	Cost	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
1. Validate the ... <i>(THIS AIM MUST WORK—i.e. no/low risk here!)</i>										
1a. Compare... confirm...			■							
1b. Optimize the dose/time course...				■	■					
2. Elucidate the mechanism... <i>(May omit for high risk (e.g. R21) grants.)</i>										
2a.			■	■	■					
2b.				■	■	*	■	■		
2c.							■	■	■	
3. Assess the biocompatibility of ... in a ... <i>(Transition to next grant.)</i>									■	■

* *High-risk element. Propose and discuss alternatives. Decision point.*

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)

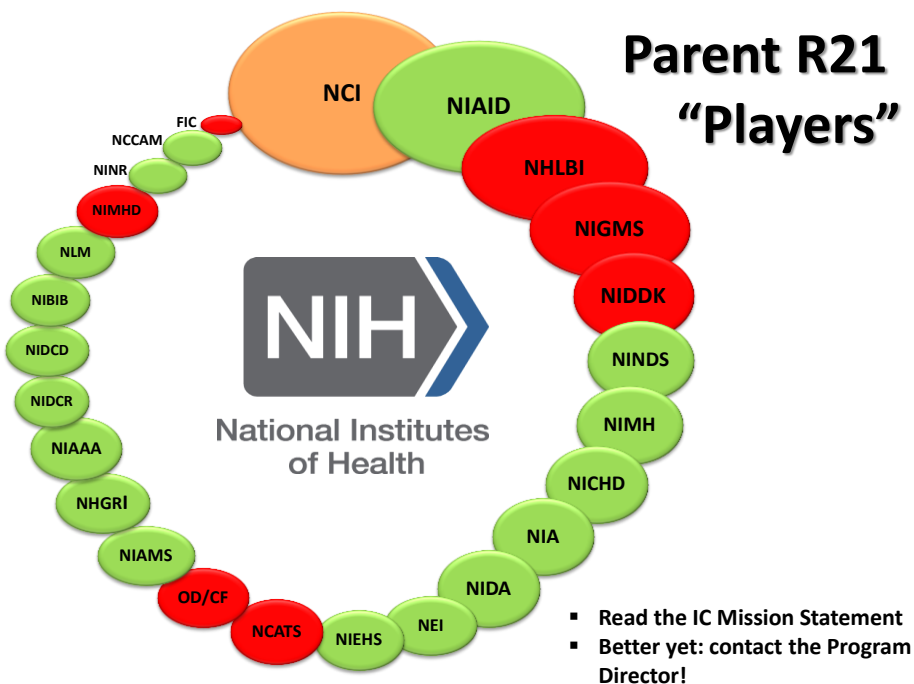
- High(er) risk and reward
- Little/no supporting data

R03 (2 yrs, \$50K per year, non-renewal)

- Little/no supporting data
- succinct task(s)

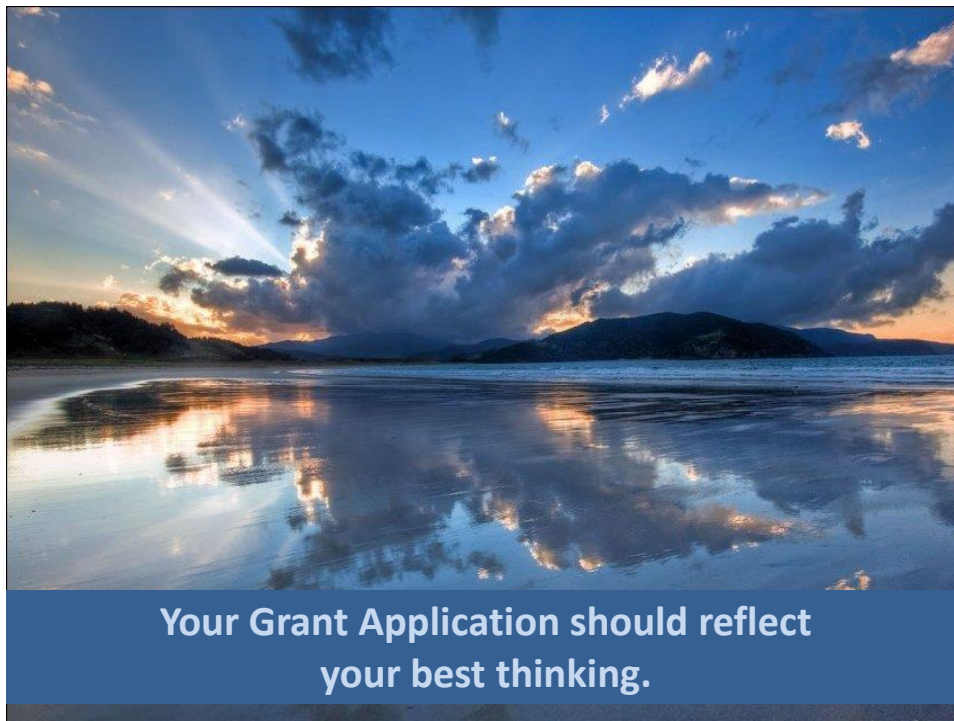
R01 (4-5 yrs, \$250 - 400K+, renewable, a "real" grant)

- Convincing preliminary data for each aim
- Longer term questions
- Multiple complexities



Elements of the Grant Application

- **Specific Aims: your key to success**
- **Research Strategy**
- **Other Considerations**
- **Funding Emerging Science, Technology Development**



Your Grant Application should reflect
your best thinking.

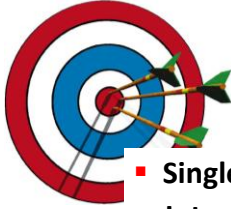
NIH Applications

Key Elements

- Cover Letter and Title Pages
- Abstract (1 page synopsis)
- Budget with Justifications
- Biosketches of Investigators
- Resources and Facilities
- Introduction (resubmissions/revisions only!)
- Specific Aims (1 page)
- Research Strategy (6 or 12 pages)
 - Significance
 - Innovation
 - Approach
 - Preliminary Studies/Progress Report
 - Experimental Design and Methods
- Bibliography and References
- 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.





$$\beta + \alpha(z^2 - i)n \times g_3 = a!$$

SPECIFIC AIMS Page: Formula for Success

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**
- **Innovation**
- **Approach**
 - Preliminary Studies/Progress Report
 - Experimental Design and Methods

RESEARCH STRATEGY - Significance: Why is this important?

- Amplify initial paragraph of the Specific Aims.
- Explain the incidence, standard of care, outcome, and costs associated with the important health related issue of the effort? How do you know?
- Define existing knowledge base via evaluating relevant and current literature. Where are the gaps?
- Will my solution matter? Assuming success, quantify and qualify the impact on:
 - Scientific knowledge
 - Technical capacity
 - Clinical practice
- A picture (figure or graph) is worth a thousand words, but be selective to emphasize (not divert from) the point.

Significance is About CONTEXT



Joshua Bell, in performance
Tickets: \$50 - \$250 each



Joshua Bell, in the DC Metro
Total receipts: \$32



- 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

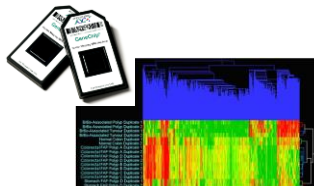
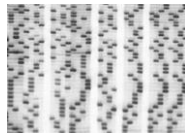
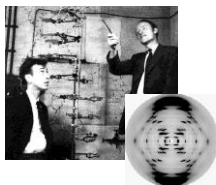
RESEARCH STRATEGY – Innovation:

How is this game changing?

- How will this effort shift current research or clinical practice paradigms?
- Is the proposed work new? Creative? Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions(s) to be developed.
- How will the results direct/inform future research?
- How will it be disseminated?
- Will success improve the “State-of-the-art”, or establish new research directions?

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

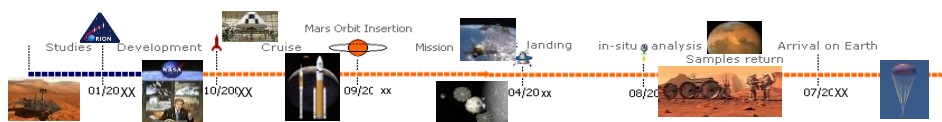
RESEARCH STRATEGY – Approach: Prior Work: What has already been done?



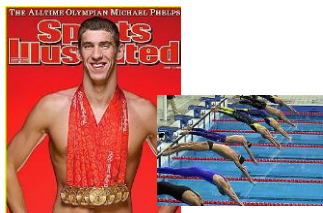
- Data must lead to the current proposal, supporting the feasibility of the proposed work
- Demonstrate that the investigator has:
 - mastery of (and/or access to) the required techniques
 - ability to manage and work with collaborators/partners
 - sufficient attention to important details (i.e. accurate, 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 OUTSTANDING** 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



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.



OHRP

Office of Human Research Protections

www.hhs.gov/ohrp

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



OLAW



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Biosketches

- **Required for all investigators**
- **List degrees, positions, honors (with dates)**
 - Early Stage or New Investigators must have appropriate training, experience
- **Personal statement: why your experience and qualifications are needed for *this* project**
 - Established investigators must demonstrate ongoing accomplishments
- **Each participant in a Multiple-PI application must show complementary and integrated expertise**
- **Publications**
 - Up to 15 peer-reviewed articles or manuscripts in press (NOT in preparation!)
 - Selections based on recency, importance, relevance to *this* application
- **Other Support: overview and distinguish from work proposed**
 - Projects completed over past three years
 - Ongoing work
 - Other pending applications



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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



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Budgetary Issues

U.S. Department of Health & Human Services www.hhs.gov

Office of Extramural Research
National Institutes of Health

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Developing Your Budget

On This Page:

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- [Allowable direct vs. allowable F&A costs](#)
- [Modular vs. Detailed Budgets](#)
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- [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

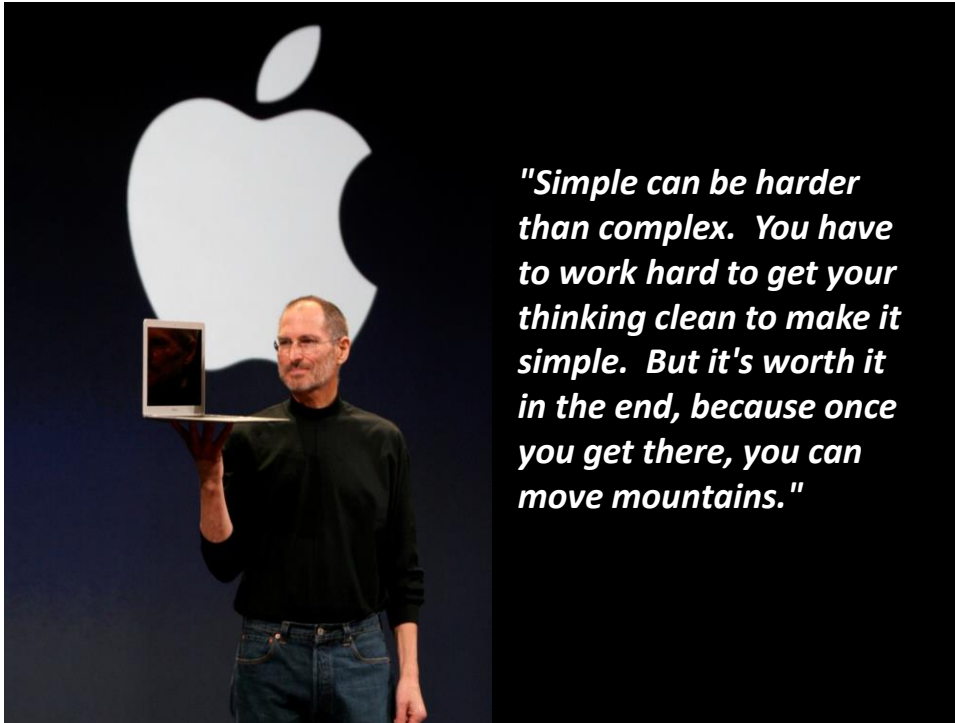
NIH funds **high risk/high reward** research if there is

- 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

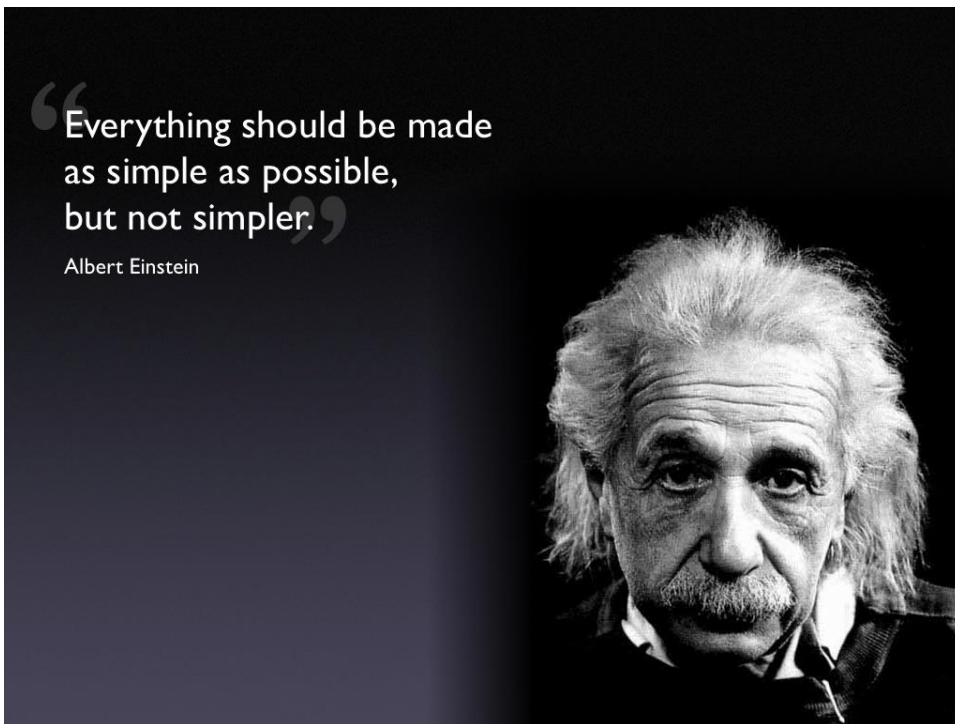


... improving health by leading the development and accelerating the application of biomedical technologies



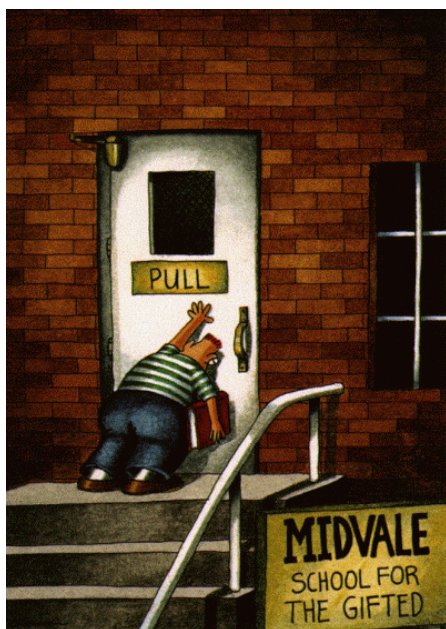


"Simple can be harder than complex. You have to work hard to get your thinking clean to make it simple. But it's worth it in the end, because once you get there, you can move mountains."



“Everything should be made as simple as possible, but not simpler.”

Albert Einstein



Know the difference
between regulations
and guidelines, and
**follow the instructions
EXACTLY!**

Do I Contact NIH *Before* Applying?

Mandatory:

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

Optional:

- When RFA's request a Letter of Intent

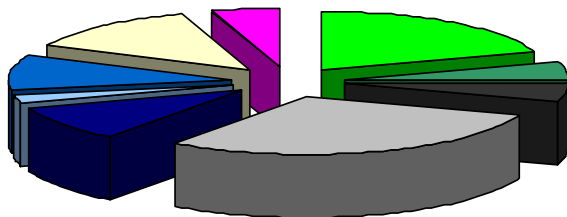
Recommended:

- When you think about applying for *any* grant



NIH Grant Application?

Read your completed draft
with a reviewers eye!



Realistically revise.

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



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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





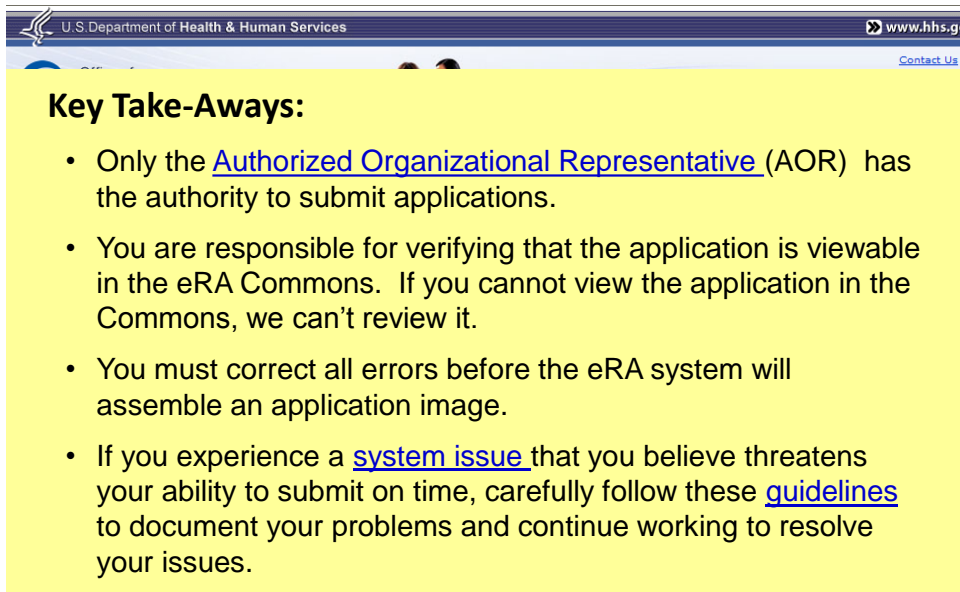
Just Send it



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Submit Through grants.gov...



U.S. Department of Health & Human Services www.hhs.gov [Contact Us](#)

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



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Once You've Successfully Submitted...

Receipt and Referral, Center for Scientific Review (CSR)

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

to an NIH Institute (IC)

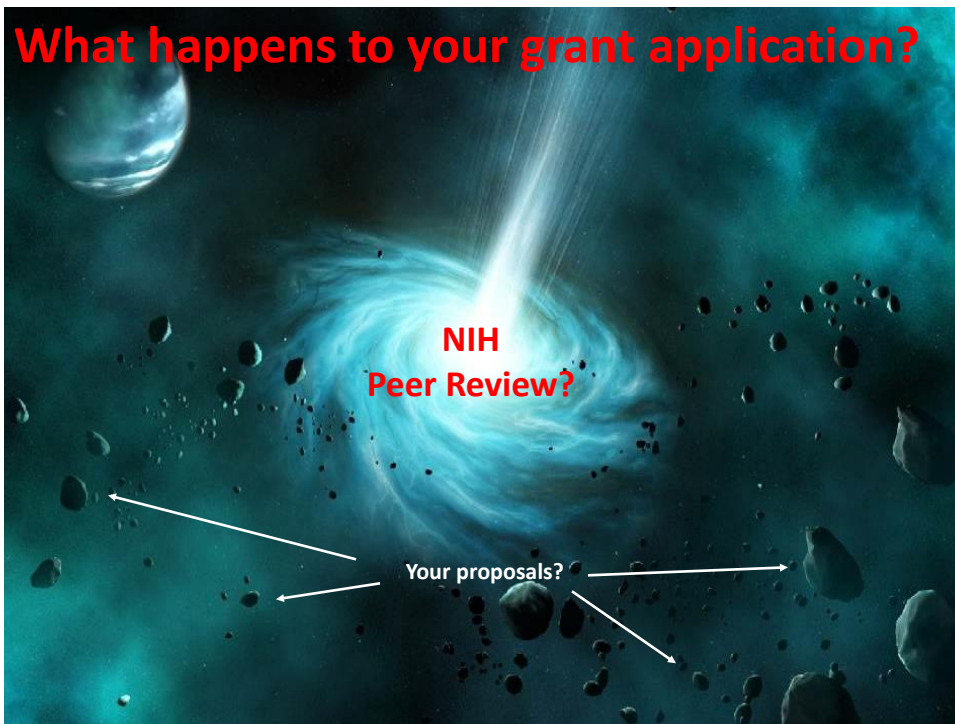
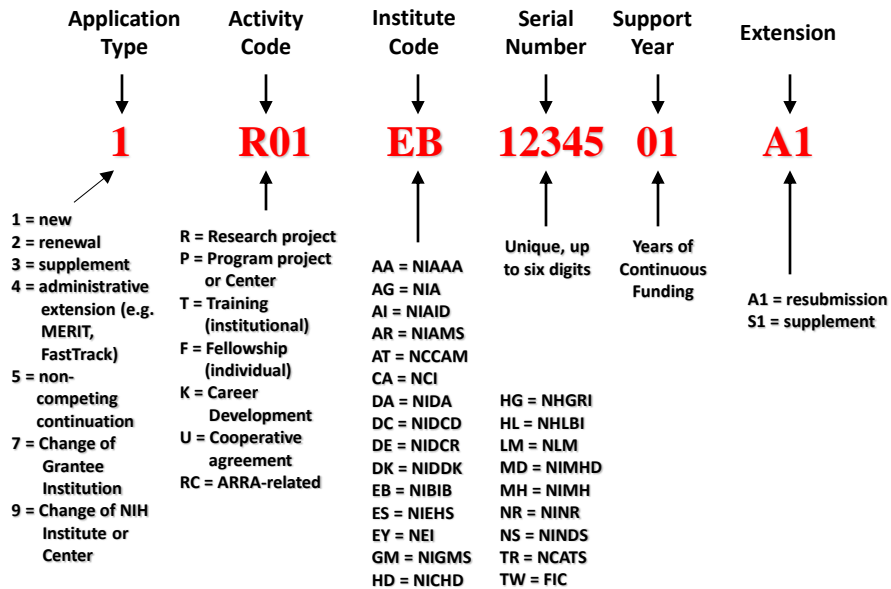
to Integrated Review
Group (IRG) and then a
study section (SRG)

a unique identifier
(application number)

Notice of assignment available in
eRA Commons in 4 weeks.

Check your eRA Commons account for updates!

Decoding Your NIH Grant Number



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

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Peer Review Policies & Practices

On This Page:

- [What's New in Peer Review](#)
- [Peer Review Archive](#)
- [Information for Reviewers](#)
- [Peer Review Practices and Policies](#)

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

- [Related Archives](#)
- [NIH Peer Review Policies and Practices \(NIH Staff Only\)](#)
- [Rosters of NIH Scientific Review Groups](#)
- [Office of Federal Advisory Committee Policy](#)
 - [Meeting Schedule for all Advisory Councils](#)
 - [More Information about each Council available on IC websites](#)
- [Enhancing Peer Review](#)
- [Peer Review Advisory Council \(PRAC\)](#)
- [Peer Review Notes](#)

Grants Policy

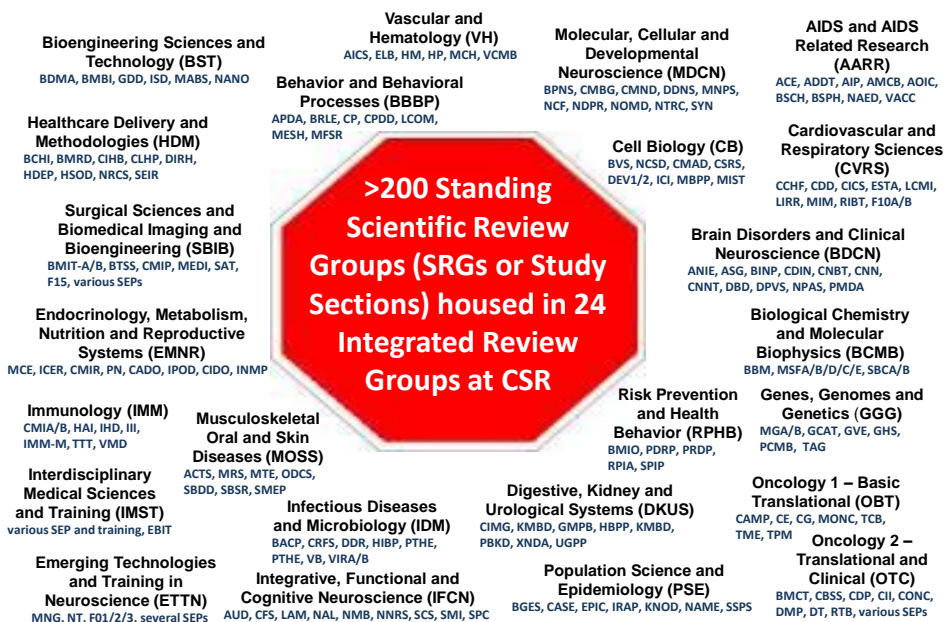
- Policy & Guidance
- Compliance & Oversight
- Research Involving Human Subjects
- Office of Laboratory Animal Welfare (OLAW)
- Animals in Research
- Peer Review Policies & Practices
- Intellectual Property Policy
- Invention Reporting (Edison)
- NIH Public Access
- Research Integrity

Global OER Resources

- Glossary & Acronyms
- Frequently Used Links
- Frequently Asked Questions

<http://grants.nih.gov/grants/peer/peer.htm>

Your application may be reviewed by one of:



How to Identify the Best Study Section

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the measure and future of science and health

NIH Program Resources | Staff Directory | Contact | Pre:

Search Words

Study Sections | Reviewer Resources | Applicant Resources | About CSR | Posters and Meetings | Employment

Integrated Review Groups | Standing | Small Business and Technology Transfer | Fellowship | Special Emphasis

CSR Home > Study Sections

Study Sections

[Share](#) [Print](#)

Find a Study Section

Applications are reviewed in Study Sections (Scientific Review Group, SRG). Integrated Review Groups (IRGs) are clusters of Study Sections based on scientific discipline.

Enter Search Keywords

Integrated 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.


[View Study Sections by Integrated Review Groups](#)

Standing Study Sections

Policy Changes

- » Notice of the National Center for Advancing Translational Sciences and Anticipated Implementation Plan
- » Ruth L. Kirschstein National Research Service Awards (NRSA) and Other Fellowship Applications: New Policy on Post-Submission Information on [Current Research](#)

<http://public.csr.nih.gov/StudySections/Pages/default.aspx>

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Search Words Search this site...

About CSR Applicant Resources Reviewer Resources **Study Sections** Rosters and Meetings Employment

Integrated Review Groups Standing Small Business and Technology Transfer Fellowship Special Emphasis

CSR Home > Study Sections > Integrated Review Groups

Integrated Review Groups

CSR Integrated Review Groups


- AIDS and Related Research IRG [AARR]
- Biobehavioral and Behavioral Processes IRG [BBBP]
- Biological Chemistry and Macromolecular Biophysics IRG [BCMB]
- Biology of Development and Aging IRG [BDA]
- Brain Disorders and Clinical Neurosciences IRG [BDCN]
- Bioengineering Sciences and Technologies IRG [BST]**
- Cell Biology IRG [CB]
- Cardiovascular and Respiratory Sciences IRG [CVRS]
- Digestive, Kidney and Urological Systems IRG [DKUS]
- Emerging Technologies and Training Neurosciences IRG [ETTN]
- Endocrinology, Metabolism, Nutrition and Reproductive Sciences IRG [EMNR]
- Genes, Genomes, and Genetics IRG [GGG]
- Healthcare Delivery and Methodologies IRG [HDM]
- Infectious Diseases and Microbiology IRG [IDM]
- Integrative, Functional and Cognitive Neuroscience IRG [IFCN]
- Immunology IRG [IMM]
- Interdisciplinary Molecular Sciences and Training IRG [IMST]

Review Groups
 Applicant IRG for A list of IRG and description groups) the review the NIH
 Click on Scientific http://
 The study few Res

» NIH Research Involving Chimpanzee
 » New Dates Investigator R01 Applications Submitted for Standard D:
 » More ...

FAQ's

» For Applicants
 » For Reviewers
 » More ...

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home search

Home > Peer Review Meetings > BST - Bioengineering Sciences and Technologies

Scientific Areas of Integrated Review Groups (IRGs)

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

Bioengineering Sciences and Technologies IRG [BST]


Printer Friendly (Complete IRG)

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.

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.

The following study sections are included within the BST IRG:

- Instrumentation and Systems Development Study Section [ISD]
- Gene and Drug Delivery Systems Study Section [GDD]
- Biomaterials and Biointerfaces Study Section [BMBI]**

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Biomaterials and Biointerfaces Study Section [BMBI]

[BMBI Membership Roster] [BMBI Meeting Rosters]

The Biomaterials and Biointerfaces Study Section (BMBI) reviews applications concerned with biologically relevant research in materials science and the interaction of materials surfaces with biological systems. Applications driven by bioengineering principles are typical. Areas of interest include the theory, principles, design and synthesis of biomaterials as well as characterization of new or existing materials. BMBI has related interests in the interactions of biomaterials with proteins, membranes, cells, and tissues. Specific areas covered by BMBI are:

- Development and characterization of biomaterials; Self-assembled materials; Design principles, material processing, and combinatorial approaches to the synthesis of new biomaterials; Biocompatibility, toxicity, structure/property relationships, and biodegradability.
- New biomaterials and fabrication techniques for tissue engineering, transport and perfusion aspects of tissue engineering, and bioreactors.
- Molecular/cellular interfacial interactions; Non-fouling and bioactive surfaces; Improved understanding of the biology-biomaterials interface; Biosurface characterization and technology; Nanoscale characterization at the nano-scale.
- Chip- and micro-array-based microtechnologies and biosensors, with a focus on biocompatibility, nonfouling surfaces, and fouling mechanisms; Including microfluidic systems, lithographic and microfluidic elements.
- Drug and gene delivery systems and nanoparticles, with a focus on the control of release, fabrication, biocompatibility, and toxicity.

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

- Gene and Drug Delivery Systems (GDD)
- Nanotechnology (NANO)
- Bioengineering, Technology, and Surgical Sciences (BTSS)
- Enabling Bioanalytical and Biophysical Technologies (EBT)
- Instrumentation and Systems Development (ISD)

Revised 12/6/2010

Review Group Description: What is the science focus?

Science Focus of "nearest neighbor" study sections

printer friendly

Home

- About CSR
- News and Reports
- Peer Review Meetings
- Resources for Applicants

BST - Bioengineering Sciences and Technologies

- Instrumentation and Systems Development Study Section [ISD]
- Gene and Drug Delivery Systems Study Section [GDD]
- Biomaterials and Biointerfaces Study Section [BMBI]
- Biodata Management and Analysis Study Section [BDMA]
- Modeling and Analysis of Biological Systems Study Section [MABS]
- Nanotechnology Study Section [NANO]
- Bioengineering Sciences and Technologies IRG [BST]

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>

You Tube NIH Peer Review Revealed...

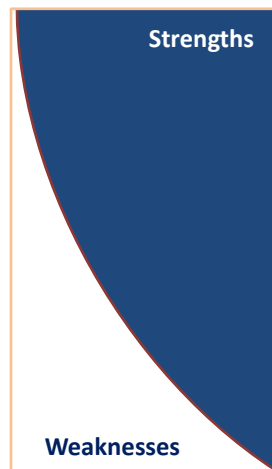


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<http://cms.csr.nih.gov/ResourcesforApplicants/InsidetheNIHGrantReviewProcessVideo.htm>

NIH Scoring System

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



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

Impact = likelihood of a sustained, powerful influence on the field

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

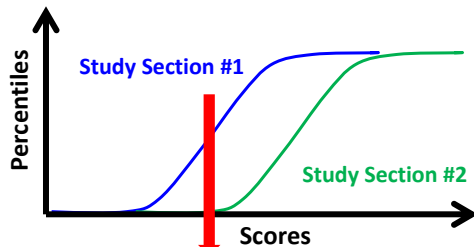
Other Elements Affecting Score

- ✓ Human/Animal Subjects Protections
- ✓ Biohazards

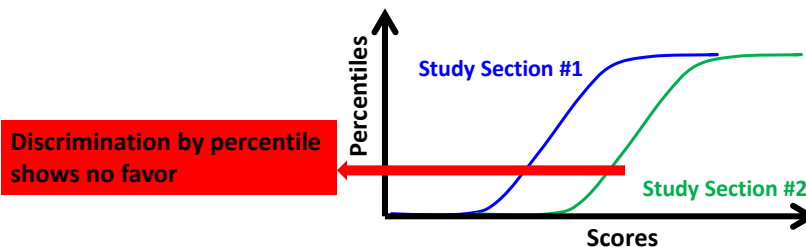
Administrative Concerns (not scorable)

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

Why Percentiles?

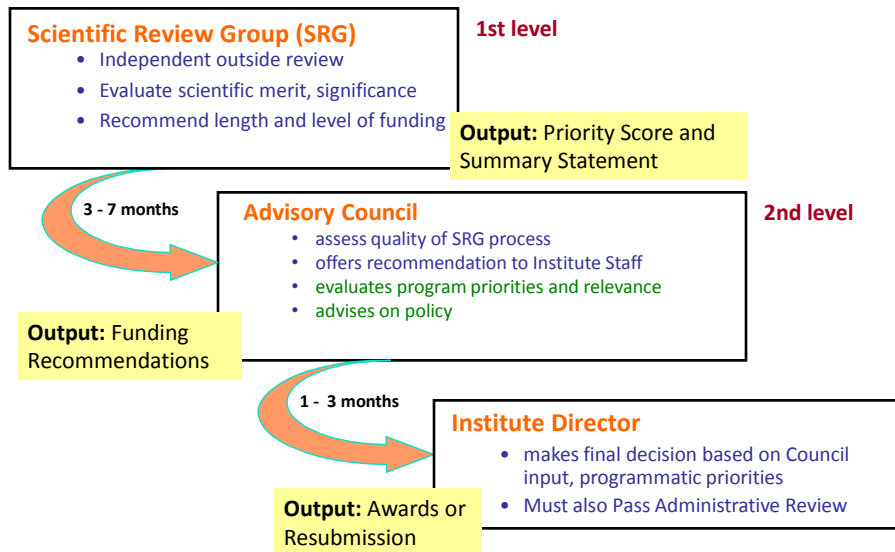


Discrimination by score favors Study Section #1



Discrimination by percentile shows no favor

NIH's Review System for Grants



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**



... or, Submit a NEW APPLICATION



The Program Official can
help you plow new ground.



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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>





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

Program Director, Tissue Engineering/Regenerative Medicine, Biomaterials and Medical Devices
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
National Institutes of Health (NIH)

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