Understanding NIH:
Drinking from the Fire-hose

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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

Different Agencies: Different Cultures

Spectrum of support

NSF
NIH
DARPA

Research basic applied Development

High Risk High Feasibility

Probability of success

Entrepreneurial Experienced

PI/Team Qualifications
NIH is the steward of medical and behavioral research for the Nation. Its mission is to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance human health, lengthen life, and reduce illness and disability.
NIH FY18 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 80% distributed via Extramural grants, contracts, cooperative agreements.
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
NIH “hot topics”

- **Essential Building Blocks of Research**
  - Mechanisms of biology and behavior, data science, new technologies
    - Cryo-Electron Microscopy
    - Human BioMolecular Atlas Program (HuBMAP)
  - Developing Effective Treatments and Cures
    - Cancer Immunotherapy
    - Tissue Chips
  - Health Promotion and Disease Prevention
    - Vaccines (e.g. influenza, Zika)
    - Environmental Influences of Child Health Outcomes (ECHO) Program

- **Implementing 21st Century Cures Act**
  - Precision Medicine Initiative (All of Us)
    - Integrating clinical, environmental, lifestyle, genetic data over time
    - Individual variability effects on disease onset, progression, prevention, treatment
    - Health records of a million volunteers
  - BRAIN Initiative
    - Fundamental science
    - Neuroimaging and mapping

- **Battling Opioid Addiction**
  - New treatments for pain
  - Understanding and managing drug misuse and overdose

Trans-NIH Programs

NIH Common Fund
Transformative – Catalytic
Synergistic – Unique
Cross-cutting

- Somatic Cell Genome Editing
- High-resolution Cryo-Electron Microscopy
- Human Biomolecular Atlas Platform (HuBMAP)
- Regenerative Medicine
- 4D Nucleome
- Library of Integrated Network-Based Cellular Signatures (LINCS)
- Global Health
- Knockout Mouse Phenotyping
- Extracellular RNA Communication
- Science of Behavior Change
- Glycoscience
- Metabolomics
- Epigenomics
- Undiagnosed Diseases
- Molecular Transducers of Physical Activity
- Genotype-Tissue Expression (GTEx)
- Proximity Capture
- Gene Expression
- Protein Capture
- Illuminating the Drugable Genome
- Gabrielle Miller Kids First
- HCS Research Collaboratory
- Biomedical Workforce
- Big Data to Knowledge
- Health Economics
- Stimulating Peripheral Activity to Relieve Conditions (SPARC)
- Early Independence
- New Innovators
- Pioneers
- Transformative R01s
- NIH Workforce Diversity
- High-risk Research
- Recurring
- Early Independence
- New Innovators
- Pioneers
- Transformative R01s

* = watch for new initiatives

http://commonfund.nih.gov/
Evolution of NIH Support...

- Enabling tools, technologies
- Early stage
- Engineering > Science

R21
- Exploratory
- High potential
- Sound thinking w/ no preliminary data

R01
- Advancing the field
- Significant, impactful
- Grounded in preliminary data

R03
- Beyond enabling
- Targeted, mechanistic
- Moving toward product Development

U01 (BRP)

... for the idea, not the person
Supporting Projects (research grants) vs People (training awards)

- **Training Grants – T (Institutional)**
  - Institutional
  - Predoctoral and Postdoctoral

- **Fellowships – F (Individual)**
  - Predoctoral – F31
  - Postdoctoral – F32

- **Career Development Awards – K**
  - Goal: increase potential, independence of NIH researcher
  - minimum 75% effort plus classwork (training)
  - move in a different direction
  - broaden, expand existing expertise
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)
- Quantity/quality of supporting data not a factor
- succinct task(s)

R01 (4-5 yrs, $250 - 400K+, renewable, a “real” grant)
- Convincing preliminary data for each aim
- Clear methodology w/ alternatives Longer term questions
- Multiple complexities
- Strong, well-integrated team
- New Investigators get 5-point bonus
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, spanning NIH mission

- **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/or “protected” review
  - Program Announcement with Set Aside (PAS) essentially, an RFA with multiple receipt dates
“Players”

- Read the IC Mission Statement
- Better yet: contact the Program Director!
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).
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

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

Scientific Review Officer...

- Point of contact during review process
- Addresses concerns about IC or Study Section Assignment
- Recruitment/Assignment of Reviewers
- Insures fair, unbiased evaluation (legally responsible for the conduct, outcome of the session)
- Provides summary statement (merit evaluation) for IC and Applicant
- Does not participate in funding decision, but supplies the evidence for a thorough evaluation of the proposed effort
NIH Institute/Center Web Sites

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.

www.nih.gov/icd/
Each NIH Institute/Center has a HOME PAGE

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

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

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 of these materials and their clinical performance.

This program supports the design, development, evaluation and validation of medical devices and implants, vis-a-vis their interface to the host. This includes: exploratory research on modifications (especially of the implant surface) that increase device integration; development of tools for assessing host-implant interactions; development of predictive models and methods to assess the useful life of devices; and explant analysis.

<table>
<thead>
<tr>
<th>GRANT NUMBER</th>
<th>PROJECT TITLE</th>
<th>PRINCIPAL INVESTIGATOR</th>
<th>INSTITUTION</th>
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<td>5-R21-EB01838-02</td>
<td>Catalytic Nitric Oxide Release Coating for Prolonged Anti-Clotting Catheters</td>
<td>Melissa Reynolds</td>
<td>Colorado State University</td>
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</table>
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
- ...
## Search Results

There were 13 results matching your search criteria. Click on the column header to sort the results.

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<tr>
<th>T Act</th>
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<th>Year</th>
<th>Sub #</th>
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<th>Contact PI/Project Leader</th>
<th>Organization</th>
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<td>05A1</td>
<td>IN VITRO BIOREACTOR SYSTEM FOR PLATELET FORMATION</td>
<td>RALDUINI, ALESSANDRA et al.</td>
<td>TUFTS UNIVERSITY MEDFORD</td>
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<td>U19</td>
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<td>CENTER FOR ENTERIC DISEASES IN ENGINEERED TISSUES</td>
<td>JSBERG, RALPH R. et al.</td>
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<td>MODELS TO PREDICT PROTEIN BIOMATERIAL PERFORMANCE</td>
<td>KAPLAN, DAVID L et al.</td>
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<td>INJECTABLE GELS FOR TISSUE AUGMENTATION</td>
<td>KAPLAN, DAVID L et al.</td>
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<td>NEI</td>
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</tbody>
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... of Useful Information.
Use “Matchmaker” for even more functionality

Copy and paste abstract (or other text) here
Lots of active links refine, focus search!
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.

https://loop.nigms.nih.gov/index.php/2012/12/03/how-to-use-reporter-when-preparing-new-grant-applications/
There are two kinds of scientific revolutions, those driven by new tools and those driven by new concepts... The effect of a concept-driven revolution is to explain old things in new ways. The effect of a tool-driven revolution is to discover new things that have to be explained.

- Freeman Dyson, 1997
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
Elements of the Grant Application

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

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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.
Strong Research Question

Medical Need

= outcomes
(low hanging fruit)

Aim 1
preliminary data
background
approach

Aim 2
preliminary data
background
approach

Aim 3
(preliminary data
background
approach

Structuring Your Grant Application
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
- Resource Authentication Appendix
  - Human Subjects
  - Other (animals, consortium, multi-PI, select agents and biohazards, 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; sells the grant
- 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; must flow logically
  - 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
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
  - Outline the problem
  - How does your past work, experience offer a solution
- 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
- Don’t over-reach
- Moving from Invention to Innovation is a good strategy: balance feasibility with bold research
RESEARCH STRATEGY – Approach: Prior Work: What has already been done?

- Often found in the “Background/Significance” section
- Data must lead to the current proposal, supporting 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
  - attention to important details (i.e. accurate, carefully assembled figures, tables, graphs)

Reviewers may NOT look anything up!
- Provide sufficient, relevant details for an informed judgment
- Publish and cite your data wisely
**RESEARCH STRATEGY - Approach:**

**Methods: How will it be done?**

- Do tasks relate to the Specific Aims?
  - Provide an overview/rationale/conceptual framework. Connect all the dots in an easy to read but concise narrative.

- 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 this rigorous? 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
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
- INCLUSION requirements have changed!
- CLINICAL TRIALS definitions have changed!!

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

www.hhs.gov/ohrp

grants.nih.gov/grants/olaw
Grant Submissions: Recent Changes

Rigor, Reproducibility, Transparency
- Scientific premise now a scorable criteria; must be justified by data
- Data processing must include statistical analysis (where applicable)
- Relevant biological variables (sex, age, etc.) must be considered in experimental design

IC Participation in R21(and R03) FOAs
- Read the Solicitation! Some ICs do not use these mechanisms
- Some ICs have their own basic versions, or use these mechanisms only for specific topics
- Amount, type of PRELIMINARY DATA a key consideration for R21

Human Subjects
- Inclusion Tables now required for all non-exempt human subjects research
- NIH defines a CLINICAL TRIAL very broadly (answer the four questions)
- FOAs recently subdivided into three types, based on clinical trials (not allowed, optional, required).
  Be sure to use the correct template!
- Clinical trials funded by NIH grants must be registered at ClinicalTrials.gov and report findings

NIH now using “Forms E” for application submission!
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
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
"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.”
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
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
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.
Special Handling?

Use Assignment Request Form to suggest
- Scientific Review Group
- Expertise necessary for a full and fair review
- Primary (and secondary) Institute or Center (IC)
- Reviewers with potential conflicts

Use Cover Letter to
- Explain late submission
- Note eligibility for continuous submission
- Acknowledge NIH approval for
  - budget >$500K/yr
  - Conference grant
- Highlight application as one of a set, if applicable

https://public.csr.nih.gov/ApplicantResources/PlanningWritingSubmitting/Pages/conveyAssignment.aspx
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

Once You’ve Successfully Submitted...

Check your eRA Commons account for updates!

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)
a unique identifier (application number)
## Decoding Your NIH Grant Number

<table>
<thead>
<tr>
<th>Application Type</th>
<th>Activity Code</th>
<th>Institute Code</th>
<th>Serial Number</th>
<th>Support Year</th>
<th>Extension</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 = new</td>
<td>R01</td>
<td>EB</td>
<td>987654</td>
<td>01</td>
<td>A1</td>
</tr>
</tbody>
</table>

- **Application Type**  
  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  

- **Activity Code**  
  R = Research project  
  P = Program, Center  
  T = Training (institutional)  
  F = Fellowship (individual)  
  K = Career Development  
  U = Cooperative agreement  
  D = Director’s award (Common Fund)  

- **Institute Code**  
  AA = NIAAA  
  AG = NIA  
  AI = NIAID  
  AR = NIAMS  
  AT = NCCIH  
  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  
  OD = Office of the Director (Common Fund)  
  NS = NINDS  
  NR = NINR  
  TR = NCATS  
  TW = FIC  

- **Serial Number** Unique, up to six digits  
- **Support Year** Years of Continuous Funding  
- **Extension**  
  A1 = resubmission  
  S1 = supplement
Now It’s Our Turn: The Review Process

- Find the Best Review Committee
- Understand the Assessment
- Responding to the Evaluation
What happens to your grant application?

NIH Peer Review?

Your proposals?
Peer Review Policies & Practices

On This Page:
- What's New in Peer Review
- Information for Reviewers
- Peer Review Practices and Policies
- Peer Review Archive

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

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, CRIS, DEV1/2, ICI, MBPP, MIST

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

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

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

Musculoskeletal, Oral and Skin Diseases (MOSS)
- ACTS, MRS, MTE, ODCS, SBDD, SBSR, SMEP

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

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, VIRA/B, F13

Behavioral Processes and Microbiology (BIBP)
- APDA, BRLE, CP, CPDD, LCOM, MESH, MFSR

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

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

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

AIDS and AIDS Related Research (AARR)
- ACE, ADDT, AIP, AMCB, AOIC, BSCH, BSPH, NAED, VACC

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

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

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

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

http://public.csr.nih.gov/StudySections/Pages/default.aspx
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]
- Molecular Cell-based Development IRG [MCBD]

FAQ's
- For Applicants
- For Reviewers
- More...
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
... or let NIH do the Work!

https://art.csr.nih.gov/ART/index.jsp?tabId=5A6B23F8F252257CA592A3AAF2F4180814558100
NIH Peer Review Revealed...

### 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.

The overall impact score is calculated as the panel average multiplied by 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 Score
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

**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

**Output:** Funding Recommendations

**1st level**

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

**Output:** Awards or Resubmission

**2nd level**

3 - 7 months

1 - 3 months
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?

- It’s not personal
- Revise and resubmit
- Reviewers are ALWAYS right, or wrong for the right reasons
- Absorb the critiques
  - make suggested changes, or
  - provide additional justification for your original approach
- Explain the changes in a one page “Introduction”
If at first you don’t succeed, redefine SUCCESS.
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)
Strategies for Success

- This is hard work
  - Allow six months to write a grant
  - Keep trying: average success is 1 in 10
- Program Officials are your best resource
- Use available technology
  - RePORTer is a rich database of funded projects
  - Exploit search tools and shortcuts
- Target submissions: specific vs parent FOAs
  - Share your Specific Aims with Program Officials
  - Think broadly, write specifically, with focus
- Do your homework and request
  - Scientific Review Group/”Study Section”
  - Institute
  - Excluded reviewers
- Appeals waste time, resources; resubmit instead
- Participate in workshops and symposia
  - Get fresh ideas and directions for your research
  - Become known to your peers (i.e. reviewers)
- Learn the ropes: serve on study sections
Start where you are. Use what you have. Do what you can. - Arthur Ashe

Hope for the best. - Rosemarie Hunziker
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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