Understanding NIH: Drinking from the Fire-hose

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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

Probability of success
- High Risk
- High Feasibility

PI/Team Qualifications
- Entrepreneurial
- Experienced
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 FY17 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 = $33 B
NIH “hot topics”

- **Essential Building Blocks of Research**
  - Mechanisms of biology and behavior, data science, new technologies
    - Cryo-Electron Microscopy
    - Single cell analysis
  - Developing Effective Treatments and Cures
    - Cancer Immunotherapy
    - Tissue Chips
  - Health Promotion and Disease Prevention
    - Vaccines (e.g. influenza)

- **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

- **Cancer Moonshot**
  - Prevention and early detection
  - Immunotherapy
  - Pediatric cancer
  - Data sharing

- **Regenerative Medicine**
  - Clinical research focus
  - Adult stem cells
  - Regulatory science (w/ FDA)

Trans-NIH Programs

- 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)
- Knockout Mouse Phenotyping
- Global Health
- Extracellular RNA Communication
- Science of Behavior Change
- Undiagnosed Diseases
- Epigenomics
- Metabolomics
- Genotype-Tissue Expression (GTEx)
- Molecular Transducers of Physical Activity
- Big Data to Knowledge
- Protein Capture
- Stimulating Peripheral Activity to Relieve Conditions (SPARC)
- Health Economics
- HCS Research Collaboratory
- Biomedical Workforce
- NIH Workforce Diversity
- NIH Workforce Recurring
- Early Independence
- New innovators
- Pioneers
- Transformative R01s
- Transformative – Catalytic
- Synergistic – Unique
- Cross-cutting

* = watch for new initiatives

http://commonfund.nih.gov/
How Does NIH Solicit Applications?

- **Federal Opportunity Announcements (FOA)** published through
  - 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
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!
Grants: A to Z

NIH National Institutes of Health
Office of Extramural Research

Grants & Funding

About Grants
- Grants Process Overview
- Grant Application Basics
- Types of Grant Programs
- How to Apply
- Peer Review Process
- Award Management
- Foreign Grants Information
- Funding Strategies
- Avoid Grant Scams

Electronic Grants
- Electronic Research Admin (eRA)

Funding
- Search NIH Guide for Grants and Contracts
- Funding Opportunities & Notices
- Unsolicited Applications (Parent Announcements)
- Advanced Search

Due Dates, Templates

Funding Initiatives

New to NIH Grants?

http://grants.nih.gov/grants/oer.htm
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 in
- Projects
- Publications
- Projects & Publications
- Project Title
- Project Terms
- Project Abstracts
- ...

Limit Publication search to
- Start Year
- End Year
- Project Number
- Format: 5R01CA12345-04
- Use % for wildcard, e.g. %R21% Enter multiple project numbers

Submit Query
Clear Query
### RePORTer Delivers a Treasure Trove...

There were 10 results matching your search criteria.

Click on the column header to sort the results.

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<th>T</th>
<th>Act</th>
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<td>TUMOR ANTIGEN-SPECIFIC T-CELLS AND HEPATOCELLULAR CARCINOMA</td>
<td>KAPLAN, DAVID E</td>
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<td>IN VITRO BIOREACTOR SYS FOR PLATELET FORMATION</td>
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Click for Abstract
... of Useful Information.

**Project Information**

5R01EB014283-02

**Project Number:** 5R01EB014283-02  
**Title:** MULTIFUNCTIONAL TROPOELASTIN-SILK BIOMATERIAL SYSTEMS  
**Contact PI / Project Leader Information:**  
- **Name:** KAPLAN, DAVID L  
- **Email:** Click to view Contact PI / Project Leader email address  

**Program Official Information:**  
- **Name:** HUNZIKER, ROSEMARIE  
- **Email:** Click to view PO email address

**Organization:**  
- **Name:** TUFTS UNIVERSITY MEDFORD  
- **City:** MEDFORD  
- **Country:** UNITED STATES (US)

**Department/ Organization Type:**  
- **Department:** BIOENGR/ENGR ENG/ENGR STA

**Congressional District:**  
- **State Code:** MA  
- **District:** 07

**Other Information:**  
- **FOA:** FA-11-260  
- **Study Section:** Gene and Drug Delivery Systems Study Section (GDD)

- **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/
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, re-scoping, 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.
- Discover what’s New and Coming Soon in Funding Opportunities
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

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

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 scaffolds; 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.

Relevant Study Sections

Biomaterials and Biointerfaces (BMBI)
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
the NIBIB distinction…
• Technology development
• Enabling tools/approaches

Featured Mechanisms
- Bioengineering grants (EBRG, BRG, BRP)
- Biomedical Technology Resource Centers (P41)
- Quantum grants
- Trailblazers: NI R21s

Featured Programs
- Multiscale Modeling Consortium
- Pediatric Research using Integrated Sensor Monitoring Systems (PRISMS)
- Point-of-Care Technologies Research Network

It’s not enough to be UNIQUE…
you must also be USEFUL.
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
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>
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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
- Preliminary data
- Outcomes (low hanging fruit)

Aim 1: Background
Aim 2: Approach
Aim 3: Preliminary data

(approach, background, (preliminary data))
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
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National Institutes of Health (NIH)

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