NIH Funding for mHealth Research

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TODAY’S AGENDA: HOW TO SUCCEED AT NIH

- What New in the:
  - NIH
- Finding your NIH Niche
  - Each IC has a unique character
  - Get help from the inside
- What New in the:
  - NIBIB
- Writing Competitive Grants
  - Organize your team and plan
  - Specific Aims are the bedrock
  - Make reviewers your advocates
- mHealth Funding & Opportunities

Thanks to Rosemarie Hunziker
NIH “hot topics”

- Cancer Moonshot ($680M)
- Precision Medicine Initiative ($200M + 100M)
- Discovery Science
  - BRAIN Initiative ($135M + 45M)
  - Microbiome and health
  - Strategic Approach to HIV/AIDS
  - Strengthen and Sustain Diverse & Talented Biomedical Research Workforce
- Translating discovery into health
  - Antimicrobial Resistance ($100M)
    - national database of germ genomes
    - prize for better diagnostics (w/BARDA)
    - antibiotics and vaccines
  - Alzheimer’s Disease ($350M)
    - basic research
    - epidemiology for risk/protective genes
    - early diagnosis and progression
- Accelerating Medicine Partnership
- Common Rule & Clinical Studies
- NIH Strategic Plan

Finding your NIH Niche
- Each IC has a unique character
- Get help from the inside
NIH FY16 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

Total = $31.3 B
NIH is organized into:

27 Institutes & Centers (IC) each with different:

- missions and priorities
- budgets
- ways of deciding which grants to fund

Centers have no funding authority
Sample IC Mission Statements

NIBIB - integrating the physical and engineering sciences with the life sciences to advance basic research and medical care

NIDCR - improve oral, dental and craniofacial health through research, training, and dissemination of health information

NIAMS - support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases, training of basic and clinical scientists for this

NHLBI - global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases

NIDDK - medical research, training and dissemination of science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases
Targeting IC Priorities: an example

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

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

Novel polymer scaffold for tissue regeneration
Neural progenitor cells in biomimetic matrix in rat brain
Pivotal large animal studies for stroke therapy

Neural differentiation of stem cells
Imaging cells transplanted to the brain
Different Grants Serve Different Purposes

- **R01**
  - Workhorse of NIH research, highly valued by peers
  - An outline for continuing rigorous investigation, provides new input for the field without gaps for others to fill
  - Based on solid preliminary data
  - 4-5 years, renewable, generally $400-$500K per year
  - **NOTE**: NIBIB funds R01s for only 4 years, renewable.

- **R03**
  - A “mini-R01” popular with new investigators
  - Self-contained: data analysis, pilots, methods development
  - $50K per year for two years

- **R21 (Exploratory/Developmental)**
  - Ideal = High Risk/High Reward (HR²)
  - Innovation is a key, preliminary data not “required”
  - $275K per year, typically 2 years, NOT renewable
  - Success = quantum leap requiring follow up and/or validation (e.g. an R01 or BRP submission)
# Small Business Innovation Research (SBIR) Small Business Technology Transfer (STTR) Programs

## PHASE I – Feasibility Study
- Average award: $170K
- Project period varies, most 6 – 12 months

## PHASE II – Full R&D
- Average $850K, 2 years but some longer
- Commercialization plan required

## PHASE III – Commercialization
- Use of non-SBIR/STTR Funds

### Issues
- Budgets inadequate for expectations
- Gap between Phases I and II can be almost two years
- Reviewers do not understand challenges of the “D” in “R&D”
Research Training and Career Awards

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

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

- **Career Development Awards** – $K$
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 (rebutding, 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
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

Limit Publication search to
- Start Year
- End Year
- Project Number
- Format: SR01CA012345-04

Use % for wildcard, e.g. %R21%
Enter multiple project numbers OR

Activity Code: 
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/
What’s New in NIBIB
What’s different about NIBIB?

• Focus on development of new technologies, probes, and platforms
• Specialize on enabling technologies with broad application to multiple diseases or biological processes
• Multi-disciplinary and collaborative research
• Support design- and needs-driven research, not just hypothesis-driven research
• Support the missions of our sister ICs
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
Scientific Program Areas

- Biomaterials
- **Biomedical Informatics**
- Delivery Systems & Devices for Drugs and Biologics
- Image-Guided Interventions
- Image Processing, Visual Perception and Display
- Integration of Implantable Medical Devices
- **Magnetic, Biomagnetic and Bioelectric Devices**
- Magnetic Resonance Imaging and Spectroscopy
- Mathematical Modeling, Simulation and Analysis

- Micro-Biomechanics
- Micro-/Nanosystems & Platforms
- **Molecular Imaging**
- Nuclear Medicine
- Optical Imaging and Spectroscopy
- Rehabilitation Engineering
- Sensors
- Surgical Tools, Techniques & Systems
- Synthetic Biology for Technology Development
- Telehealth
- Tissue Engineering
- **Ultrasound: Diagnostic & Interventional**
- X-ray, Electron, and Ion Beam
NIH Bioengineering Program Announcements

- **PA-12-284**: Exploratory/Developmental Bioengineering Research Grants (EBRG) (R21)
  
  *early and conceptual stages of new exploratory and developmental research that may involve considerable risk but may lead to a breakthrough*

- **PA-13-137**: Bioengineering Research Grants (BRG) (R01)
  
  *integrated, systems approach to basic and applied multidisciplinary research that addresses important biological, clinical or biomedical research problems*

- **PAR-14-092**: Bioengineering Research Partnerships (BRP) (R01)
  
  *team approach to basic, applied, and translational multidisciplinary research to establish a robust engineering solution to a biomedical problem*
BioTechnology Resource Centers (P41)

- Strong foundation of Technology Research & Development (TR&D) Projects
  - national/international impact
  - innovative, cutting-edge
  - complex, multidisciplinary
  - high-risk test beds leading to practical tools

- Driven by needs of the field through robust Collaborative Projects (CP)
  - dynamic, push-pull relationships

- Deploying results via Service Projects (SP)
  - geographically diverse
  - technology push
  - exploit more mature capabilities of the Center

- Committed to training practitioners

- Aggressive dissemination
  - research papers, reviews
  - patents
  - presentations, workshops
  - website(s)

- Seamless Oversight
  - experienced TR&D Leaders
  - Scientific Advisory Board
  - institutional Support
NIBIB’s Quantum Grants: Medical Moonshots
(PAR-15-031)

- profound impact
- prevent/diagnose/treat a major disease
- technology development
- 12 years (4 year grant, twice renewable)
- deliverable-focused, milestone-driven
- $1M direct costs per year
- due dates: January 26, 2016 and 2017

Current projects:
- Point-of-care Microfluidics for Early Detection of Cancer (Mehmet Toner)
- Influenza vaccine using a microneedle patch (Mark Prausnitz)
- Optimizing Cardiovascular Device Thromboresistance for Eliminating Anticoagulants (Danny Bluestein)
- Neurovascular Regeneration (Karen Hirschi)
- Building an Implantable Artificial Kidney (Shuvo Roy)
- One Stop Shop Imaging for Acute Ischemic Stroke Treatment (Guang-Hong Chen)
Bioengineering Research: Exploratory Grants (R21) - (PA-12-284), Grants (R01) - (PAR-13-137), Partnerships (R01) - (PAR-14-092)

- Design and Development of Novel Technologies for Healthy Independent Living (R01/R21) – (PAR-14-118 & -119)

- Indo-US Collaborative Program on Affordable Medical Devices (R03) – (PAR-13-390)

- mHealth Tools for Individuals with Chronic Conditions to Promote Effective Patient-Provider Communication, Adherence to Treatment and Self-Management (R01/R21) – (PA-14-180 & 181)

- NIBIB Biomedical Technology Resource Centers (P41) – PAR-13-376

- Training Opportunities: Postdoctoral, Junior Investigator, Clinician-Scientist, Diversity

- Also: Investigator Initiated R01, R21, R03, P41, P30, T32, F30/31/32, K25, K99/R00, SBIR/STTR’s...

http://www.nibib.nih.gov/funding/funding-opportunities

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

- Organize your team and plan
- Specific Aims are the bedrock
- Make reviewers your advocates
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

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.
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?

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
Do I Contact NIH *Before* Applying?

**Mandatory:**
- Application with budget ≥$500,000 direct costs for any single year. NIBIB requires a whitepaper
- R13 Conference Grants

**Optional:**
- When RFAs request a Letter of Intent

**Strongly Recommended:**
- R21 and R03 applications – Not all ICs accept, *will* return unreviewed if no “home” can be found.
- When you think about applying for *any* grant
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
"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.”
How to Win Over the Peer Reviewers

- Own impact: tackle an important and difficult problem
  - Engineers beware: lead with an urgent issue, NOT your cool tools/technologies
  - Discovery (basic) science vs. technology development (non-hypothesis driven)

- Hit all Review Criteria on the “Specific Aims” page

- Balance “the possible” with “the exciting”
  - feasibility = most relevant preliminary data + sound, logical pathway
  - Defend assertions with publications (citing reviewers a plus)
  - inspiration << invention = innovation
  - short term objectives inform long term goals
  - milestones > bold, general ideas
  - experience, expertise count

- Define success and point to the next grant/activity

- Good grantsmanship
  - limit jargon/acronyms
  - reinforce (don’t repeat) important ideas
  - use legible/sensible figures
  - strategically place an overview as “eye candy”
  - proofread!
If you want something in your life you’ve never had, you’ll have to do something you’ve never done.

- JD Houston
Take Home Messages

Lots of directions and opportunities at the NIH


- Get to know the Program Director(s) for your scientific area and discuss your ideas
  - Fit with institute mission and priorities
  - Best grant mechanism or program
  - Best study section for review

- Participate in workshops and symposia
  - Get fresh ideas and directions for your research
  - Become known to your peers (i.e. reviewers)

- Participate in review of grant applications (serve on study sections)
Path to Success at NIH

Step #1: Do your homework; learn a bit about the grant process and the options.

Office of Extramural Research:

IC priorities: http://www.nih.gov/icd/index.html

NIH Guide Provides Weekly Updates on Funding Opportunities: http://grants.nih.gov/grants/guide/

NIH RePORTer – lots of statistics and abstracts of funded grants http://report.nih.gov/

Step #2: Contact us because...
  We’re from the Government, we’re here to help you!
NIH mHealth Funding
mhealth
Mobile Sensor Data-to-Knowledge (MD2K)

Mobile Sensors
- Smartwatch
- Chestbands
- Smart Eyeglasses

Exposure

Behaviors

Outcomes

Advancing biomedical discovery and improving health through mobile sensor big data

Cornell Tech ▶ Georgia Tech ▶ U. Memphis ▶ Northwestern ▶ Ohio State ▶ Open mHealth
Rice ▶ UCLA ▶ UC San Diego ▶ UC San Francisco ▶ UMass Amherst ▶ U. Michigan ▶ WVU
Health ePeople Resource for Mobilized Research

Platform for mHealth Research

Cohort for Research

mHealth Data Repository

PI: Jeff Olgin, UCLA

Contact: Carol Maguire [Carol.Maguire@ucsf.edu]
HeP Structure

Participant Portal & Consent

Data Collection Modules

Resource Database

Data Access Modules

HeP

HeH

HeX

CTSI

Other

Cohort

Trial

Other

Onboarding + Consents

eVISIT + Other Activities

Surveys

Apps

Devices

Medical Records

Social Network

HeP Databases

HeP Data Repository

Study Management Portal

Analytics Portal

Collaborator & Study Setup Portal

CDRNs

Imaging Data

Medical Records

dbGAP
mHealth Funding Opportunities
Mobile Health: Technology and Outcomes in Low and Middle Income Countries (R21)

R21 Exploratory/Developmental Research Grant

Reissue of PAR-14-028

The purpose of this Funding Opportunity Announcement (FOA) is to encourage exploratory/developmental research applications that propose to conduct research to develop or adapt innovative mobile health (mHealth) technology specifically suited for low and middle income countries (LMICs) and determine the health-related outcomes associated with implementation of the technology. Of highest interest are innovative, well-designed multidisciplinary projects that aim to generate generalizable knowledge for the field.

The overall goal of the FOA is to contribute to the evidence base for the use of mobile technology to improve clinical outcomes and public health while building research capacity in LMICs and establishing research networks in this area. Applicants are required to propose partnerships between at least one U.S. institution and one LMIC institution and the proposed research plan should strengthen the mHealth research capabilities at the LMIC institution.
mHealth Tools for Individuals with Chronic Conditions to Promote Effective Patient-Provider Communication, Adherence to Treatment and Self-Management (R21)

**R21 Exploratory/Developmental Grant**

- [NOT-OD-16-004](#) - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015)
- [NOT-OD-16-006](#) - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals (November 18, 2015)
- [NOT-OD-16-011](#) - Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications (November 18, 2015)
- **June 4, 2014** - Notice [NOT-14-074](#) supersedes instructions in Section III.3 regarding applications that are essentially the same.

**PA-14-181**

The purpose of this initiative is to stimulate research utilizing Mobile Health (mHealth) tools aimed at the improvement of effective patient–provider communication, adherence to treatment and self-management of chronic diseases in underserved populations. With the rapid expansion of cellular networks and substantial advancements in Smartphone technologies, it is now possible - and affordable - to transmit patient data digitally from remote areas to specialists in urban areas, receive real-time feedback, and capture that consultation in a database. These mHealth tools, therefore, may facilitate more timely and effective patient-provider communication through education communication around goal setting, treatment reminders, feedback on patient progress and may improve health outcomes. This announcement encourages the development, testing and comparative effective analysis of interventions utilizing mHealth technologies. There is also an interest in studying mHealth technologies in underserved populations.
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Smart and Connected Health

The goal of the Smart and Connected Health (SCH) Program is to accelerate the development and use of innovative approaches that would support the much needed transformation of healthcare from reactive and hospital-centered to preventive, proactive, evidence-based, person-centered and focused on well-being rather than disease. Approaches that partner technology-based solutions with biobehavioral health research are supported by multiple agencies of the federal government including the National Science Foundation (NSF) and the National Institutes of Health (NIH). The purpose of this program is to develop next generation health care solutions and encourage existing and new research communities to focus on breakthrough ideas in a variety of areas of value to health, such as sensor technology, networking, information and machine learning technology, decision support systems, modeling of behavioral and cognitive processes, as well as system and process modeling. Effective solutions must satisfy a multitude of constraints arising from clinical/medical needs, social interactions, cognitive limitations, barriers to behavioral change, heterogeneity of data, semantic mismatch and limitations of current cyberphysical systems. Such solutions demand multidisciplinary teams ready to address technical, behavioral and clinical issues ranging from fundamental science to clinical practice.
Call for Late-Breaking Research Abstracts & Demonstrations

Late-Breaking Submissions Due: September 6, 2016
Decision Notification: September 15, 2016

This category is not intended to offer a second deadline for regular abstract submissions and the following rules apply:
- Abstracts should be no longer than 500 words.
- Abstracts should follow the IEEE PDF Abstract Submission Format.
- Abstracts will not be included in the conference proceedings and the IEEE Digital Library.
- Posters and demos will be presented throughout the conference with a dedicated poster session during the reception.
- A limited number of accepted submissions will be chosen for rapid--re oral presentation in addition to poster sessions.

To submit, click here and scroll to the bottom of the page and click on Papercept System.

For questions, please contact Donna Spruijt-Metz, e-mail: dmetz@usc.edu