Overview of Funding Opportunities in mHealth

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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.

Total = $37.1 B

~ 85% distributed via extramural grants, contracts, cooperative agreements

Unique IC priorities – *an example*

**Develop in vivo biosensors that allows continuous monitoring of body chemistries**

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

*“research, training, and education program to promote the prevention and treatment of heart, lung, and blood disorders”*

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*Develop a platform of biosensors that can report reliable tissue oxygen levels at various regions of interest, both acutely and long-term via mobile technologies*

*Clinical trials for a developed technology that monitors compromised tissue specifically for peripheral artery disease that results in narrowing of blood vessels and reduced blood flow to the lower limbs*
Program Portfolios

Division of Health Informatics Technologies
- Biomedical Informatics
- Connected Health
- Image Processing, Visual Perception and Display
- Point of Care Technologies

Division of Applied Science & Technology
- Image-Guided Interventions
- Magnetic Resonance Imaging
- Bio-Electromanetic Technologies
- Molecular Imaging
- Nuclear Medicine
- Optical Imaging and Spectroscopy
- Ultrasound: Diagnostic and Interventional
- X-ray, Electron, and Ion Beam

Division of Discovery Science & Technology
BIOENGINEERING
- Biomaterials
- Biosensors
- Delivery Systems and Devices for Drugs and Biologics
- Immunoengineering*
- Mathematical Modeling, Simulation and Analysis
- Microfluidic Bioanalytical Systems
- Rehabilitation Engineering and Implantable Medical Devices
- Surgical Tools, Techniques and Systems
- Synthetic Biology for Technology Development
- Tissue Chips
- Tissue Engineering
NIBIB Funding Opportunities

- NIBIB Listserv
- NIBIB Connected Health Listserv
- Program Pointers Webinar-Connected Health
  July 27, 2018
  2:00 PM ET

<table>
<thead>
<tr>
<th>Funding Opportunity Announcement</th>
<th>FOA Number</th>
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<tbody>
<tr>
<td>Mobile Health: Technology and Outcomes in Low and Middle Income Countries (R21)</td>
<td>PAR-18-242</td>
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<tr>
<td>NIBIB Trailblazer Award for New and Early Stage Investigators (R21)</td>
<td>PAR-18-207</td>
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<tr>
<td>Improving Patient Adherence to Treatment and Prevention Regimens to Promote Health (R01)</td>
<td>PA-18-722</td>
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<tr>
<td>mHealth Tools for Individuals with Chronic Conditions to Promote Effective Patient-Provider Communication, Adherence to Treatment and Self-Management (R01 and R21)</td>
<td>PA-18-386, PA-18-389</td>
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<tr>
<td>Technologies for Healthy Independent Living for Heart, Lung, Blood and Sleep Disorders (R43)</td>
<td>RFA-HL-19-016</td>
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<tr>
<td>Academic-Industrial Partnerships for Translation of Technologies for Diagnosis and Treatment (R01 - Clinical Trial Optional)</td>
<td>PAR-18-530</td>
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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**
  - All of Us (Precision medicine)
    - 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)
Tiffani Bailey Lash, Ph.D.
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NINR mHealth FOAs

mHealth Technology Showcase
June 4, 2018
Self-Management
Improving quality of life for those with chronic illness

Symptom Science
Promoting personalized health strategies

Wellness
Promoting health and preventing illness

End-of-Life and Palliative Care
Science of compassion

Technology and Training
Technological developments and tools, & training the next generation of forward-thinking nurse scientists
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.
This Funding Opportunity Announcement (FOA) seeks clinical research focused on the development and utilization of technologies that can help address patient outcomes. Relevant areas of technology include remote healthcare delivery to patients via telehealth, robotics to enhance medication adherence, on-site (e.g., clinical or home setting) care delivery, mobile health to increase access and adherence, web-based decision support tools, and others. Research projects may focus on assessment, diagnosis, intervention development, or intervention implementation. Research projects that a) incorporate emerging and cutting edge technologies to explain and predict patient trajectories, b) inform interventions, c) support real-time clinical decision making, and d) facilitate effective long-term management of chronic illness are especially needed. Critical to this FOA, proposed research should identify specific patient outcomes expected to improve from technological approaches. The specific tools or interventions proposed should clearly indicate how they will enhance patient benefits in environments, such as clinical settings, and/or in the home and community.
National Institute on Aging Small Business (SBIR/STTR) Awards to Advance Research on Alzheimer’s Disease (AD) and AD–Related Dementias (ADRD)

NIH mHealth Showcase
June 4th, 2018

Dr. Yuan Luo
Email: Yuan.Luo@nih.gov

Dr. Michael-David A.R.R. Kerns
Email: Michael-David.Kerns@nih.gov
NIH SBA Program aims to support the development and commercialization of new therapies, novel devices, analytical tools, health care programs and practices that will improve prevention and treatment, as well as caregiving for patients with AD/ADRD.

**NIA SBIR/STTR Obligations**

**Dollars in Millions**

<table>
<thead>
<tr>
<th>Year</th>
<th>Dollars in Millions</th>
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<tbody>
<tr>
<td>2013</td>
<td>$27.5</td>
</tr>
<tr>
<td>2014</td>
<td>$32.4</td>
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<tr>
<td>2015</td>
<td>$34.2</td>
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<tr>
<td>2016</td>
<td>$49.7</td>
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<tr>
<td>2017</td>
<td>$67.2</td>
</tr>
<tr>
<td>2018</td>
<td>$84.6</td>
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*estimate
NIA mHealth-related SBIR/STTR funding opportunities

1. PAR-18-187 (SBIR); PAR-18-188 (STTR)

Advancing Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R43/R44)

• Prevention - Behavioral, environmental, pharmacological, & nutritional interventions
• Diagnosis - Develop new cost-effective, minimally-invasive biomarkers for MCI
• Treatment - Discovery, development, evaluate drugs, or natural products
• Care - New technologies for in-home use for individuals with MCI or AD/ADRD
• Tools – Evidence-based interventions to reduce the burden for AD/ADRD caregivers

Award Budget- Statutory guidelines -$150K (Phase I), $1.0M (Phase II)
For waiver topics (AD/ADRD) & with appropriate justification: >$225K (Phase I) , >$1.5M (Phase II)

**Applicants are strongly encouraged to contact NIA program officials prior to submitting any application in excess of the guidelines**
NIA mHealth-related SBIR/STTR funding opportunities

2. PAR-17-067 (SBIR), PAR-17-066 (STTR)
Tools for Clinical Care and Management of Alzheimer's Disease (AD) and its Commorbidities

3. PAR-18-186 (SBIR), PAR-18-185 (STTR)
Development of Socially-Assistive Robots (SARs) to Engage Persons with Alzheimer's Disease (AD) and AD-Related Dementias (ADRD), and their Caregivers

4. PAR-18-329 (SBIR); PAR-18-326 (STTR)
Technology to Detect, Monitor and Assess Daily Functions in Individuals with Cognitive Decline, Alzheimer's Disease and/or Alzheimer's Disease Related Dementias (AD/ADRD)

Award Budget- Statutory guidelines - $350K (Phase I), $2.0M (Phase II)

**Applicants are strongly encouraged to contact NIH program officials prior to submitting any application in excess of the guidelines**
Fogarty International Center

Mission
The Fogarty International Center is dedicated to advancing the mission of the National Institutes of Health (NIH) by supporting and facilitating global health research conducted by U.S. and international investigators, building partnerships between health research institutions in the U.S. and abroad, and training the next generation of scientists to address global health needs.

Vision
The Fogarty International Center's vision is a world in which the frontiers of health research extend across the globe and advances in science are implemented to reduce the burden of disease, promote health, and extend longevity for all people.

www.fic.nih.gov
The Fogarty Pipeline

Research

Training

Individuals

• Post-Doc
• Doctoral
• Graduate
• College

Networks

Infections

mHealth

Environment

Institutions

Foreign

Domestic

STRENGTHENING

Chronic
Mobile Health: Technology and Outcomes for Low and Middle Income Countries (R21)

- Encourages exploratory/developmental research to develop or adapt innovative 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.

- Goals:
  1) Contribute to the evidence base for the use of mobile technology to improve clinical outcomes and public health
  2) Build research capacity and expertise in LMICs in this area

- Participating ICOs: FIC, NCI, NIBIB, NIDCD, NICHD NIMH, OBSSR
Mobile Health: Technology and Outcomes for Low and Middle Income Countries (R21)

• Special Considerations
  - Applicants are required to propose partnerships between at least one U.S. institution and one LMIC institution.
  - Principal Investigators may be employed in either a U.S. or an LMIC institution, but should incorporate research capacity strengthening in mHealth research in the LMIC institution(s).
  - Collaborative projects combining expertise in many relevant disciplines are highly encouraged.
  - Small grants (2 year, $125,000/year)
  - Innovation!
Mobile Health: Technology and Outcomes for Low and Middle Income Countries (R21)

Application Due Date:  Aug 31, 2018

More Information:
http://www.fic.nih.gov/Programs/Pages/mhealth.aspx (with links to funded grants)

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Mobile and Wireless Health Research at the NSF

Wendy Nilsen, PhD
Program Director, Smart and Connected Health
Computer and Information Science and Engineering

- Health, medical and rehabilitation research can be found in many areas in NSF and within the mission of several cross-directorate initiatives.
- It is a case of use-inspired basic research. The scientific advances in basic science can be in computing, information science, engineering or social or behavioral science. The benefit to health research is important, but second to the advances in basic science.
- Major homes for this research:
  - Smart and Connected Health
  - Cyber-physical Systems
  - National Robotics Initiative 2.0
  - Smart and Connected Communities
  - Core Programs
Pasteur’s Quadrant

Donald E. Stokes, Pasteur's Quadrant - Basic Science and Technological Innovation, Brookings Institution Press, 1997
Goal: Seek improvements in safe, effective, efficient, equitable, & patient-centered health through innovations in fundamental computer & information sciences, engineering & social, behavioral & economic sciences

- **Funded** work must include & address:
  - A key health problem
  - Fill in research gaps that exist in science & technology in support of health & wellness
  - Include a research team with appropriate expertise in the major areas involved in the work

- Activities should **complement** rather than duplicate core programs of NSF & NIH as well as those of other agencies (ex. Agency for Healthcare Research and Quality / Veteran's Administration)
Smart Health Research Areas (included, but not limited to)

**Health Information Infrastructure**
- Integration of EHR, contextual, clinical and patient data
- Access to information, data linkages
- Tools to enhance smart health research

**Connected Data**
- Heterogeneous and messy data
- Data fusion and optimization
- Datamining, machine learning, deep learning
- Inference, visualization, decision support system

**Connected Systems**
- Closed and human-in-the-loop systems
- Tools for connecting systems within systems
- Enhancing knowledge flow across the entire system

**Connected People**
- Enhancing communication between providers, patients and caregivers
- Assistive technologies embodying computational intelligence

**Connected Data**
- Reasoning with heterogeneous data under uncertainty

**Connected Systems**
- Multifunctional devices connected to systems

**Connected People**
- Effective, multidirectional flows of information and support
Cyber-Physical Systems
NSF 17-529

- Cyber-physical systems (CPS) are engineered systems that are built from, and depend upon, the seamless integration of computational algorithms and physical components. Advances in CPS will enable capability, adaptability, scalability, resiliency, safety, security, and usability that will far exceed the simple embedded systems of today.
  - Closed Loop
  - Human in the Loop
CPS Research is at the Central to Smart Systems: Sensing, Computation, and Control

Environment Sensing

Percepts (sensors) → Agent (Reasoning) → Pervasive Computing

Emergency Response

Situation Awareness: Humans as sensors feed multi-modal data streams

People-Centric Sensing

Personal Sensing → Public Sensing → Social Sensing

Smart Hearth Care

Informatics

Evaluate, Sense, Identify, Intervene, Assess

Source: Sajal Das, Keith Marzullo

Credit: Image courtesy of University of Florida
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Bill and Melinda Gates Foundation funding summary

In 2016, the foundation invested US $4.6 billion in these areas.

Numbers include grants and direct charitable expenses (DCE), but do not include Program Related Investments (PRIs)

- **Global Health Program**: $1.197B
  - TB, HIV, Malaria...
  - Discovery and Translation
  - Innovative Technology Solutions
- **Global Development Program**: $2.211B
- **United States Program**: $496M
- **Global Policy & Advocacy**: $513M
- **Communications**: $33M
- **Other Charitable Programs**: $111M
We focus on quantitative measurement and using data in mHealth

ITS uses technology trends to disrupt how we work

Examples non-mHealth:
- African central lab devices
- AI-based drug discovery tools
- New DNA-based vaccine platforms

Examples not in ITS:
- Chronic disease mgmt.
- Continuing medical education
- Setting data standards
- Subjective care algorithms

Examples in scope:
- Objective “measuring sticks”: 1) disease and 2) physiological
- Interfaces to improve test administration and digitize outputs
- Agent-based care using objective AND contextual algorithms
Bayesian diagnostics: ROC curve combined with prevalence

- In clinical use the **pre-test probability** is either:
  - **Static and generalized**: Determined by a clinical practice guideline based on static representations of general population-based prior probabilities
  - **An expert heuristic**: Positive and negative predictive value (PPV and NPV) often guessed by expert
- Prior probability can vary widely based on time, location, or other factors → **test interpretation should vary as well**
- **Automated Bayesian calculations** could improve PPV and NPV of tests based on real-time calculations of priors

\[
PPV = \frac{\text{True Positive}}{\text{True Positive} + \text{False Positive}}
\]

\[
= \frac{sensitivity \times prevalence}{sensitivity \times prevalence + (1 - specificity) \times (1 - prevalence)}
\]

**Example for malaria high-sensitivity testing**

<table>
<thead>
<tr>
<th>Pf prevalence</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0%</td>
<td>97%</td>
<td>95%</td>
<td>51%</td>
</tr>
<tr>
<td>1.0%</td>
<td>99%</td>
<td>99%</td>
<td>50%</td>
</tr>
<tr>
<td>0.1%</td>
<td>99%</td>
<td>99%</td>
<td>9%</td>
</tr>
</tbody>
</table>
We are looking for partners with key elements of a Bayesian diagnostic system in place

**Population prior**
(e.g. IHME, CDC, Google Epi)

**Individual prior**
(e.g. Universal decentralized “Medical Wallet”)

**Analytical performance of clinical diagnostic devices**
(e.g. ROC curves for Malaria RDT, x-ray, ultrasound)

**Ground truth with research tools**
(e.g. PCR)

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Centralized systems

Healthcare Worker

**Population prior**

**Individual prior**

**Analytical performance of clinical diagnostic devices**

**Ground truth with research tools**

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Analytics layer

Clinical decision

**Clinical decision**
NOT based on test results

Are PPV and/or NPV above minimum thresholds?

**Perform test**

Clinical decision based on test result

**Patient follow-up**
to determine outcome/impact
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