Director’s Report

National Advisory Council for Biomedical Imaging and Bioengineering

January 19, 2021

Bruce J. Tromberg, Ph.D.
Director
National Institute of Biomedical Imaging and Bioengineering
Thank You!

Extramural Science Programs

Ahmad El-Hendawy
Scientific Program Analyst 2018-2021
Division of Interdisciplinary Training

Intramural Research Programs

Sumit Chaturvedi, Visiting Fellow (Dynamics of Macromolecular Assembly)
Yaya Cheng, Special Volunteer (Laboratory of Molecular Imaging and Nanomedicine (LOMIN))
Liangcan He, Special Volunteer (LOMIN)
Meijuan Jiang, Special Volunteer (LOMIN)
Joseph Lau, Post Doc Visiting Fellow (LOMIN)
Yuanyuan Ma, Special Volunteer (LOMIN)
Laura Reyes, Post Doc, (Quantitative Medical Imaging)
Anandakumar Shunmugavel, Post Doc (Quantitative Medical Imaging)
Guocan Yu, Visiting Fellow (LOMIN)

Office of Administrative Management

Mark Rotariu, Senior Budget Analyst
Chuck Benjamin, Security SME IT
Thank You!

Extramural Science Programs

Ahmad El-Hendawy
Scientific Program Analyst 2018-2021
Division of Interdisciplinary Training

David Grainger PhD
University of Utah

Council Term ended May 2020
Stayed on thru Jan 2021
New NIBIB Staff

Extramural Science Programs

Afrouz Anderson, Ph.D.
Program Director – Optical Imaging
DAST

Jennifer Jackson, Ph.D.
Health Science Policy Analyst
OPESP

Judy Wawira Gichoya, M.D., M.S.
Data Scholar
DS-I Africa

Grace Zhou
Fellow
DDST

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FY21 Appropriations Summary

- NIH - $42,934,000,000 (increase of $1,250,000,000 above FY20 level, or 3% increase)
- NIBIB 410,728,000 ($7,090,000 above FY20 enacted level of $403,638,000, 1.8% increase)
- NIH Emergency appropriation (supplement #5): $1.25B
  -$100,000,000 for RADx
  -$1.15B for research & trials on COVID-19
# Budget Update: COVID-19 Funding

<table>
<thead>
<tr>
<th>Program/Source</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronavirus Aid, Relief, and Economic Security (CARES) Act (PL 116-136)</td>
<td>$60,000,000</td>
</tr>
<tr>
<td>Care Enhancement Act (PL 116-139)</td>
<td>$500,000,000</td>
</tr>
<tr>
<td>NIH Office of Director RADx ATP</td>
<td>$230,000,000</td>
</tr>
<tr>
<td>Biomedical Advanced Research and Development Authority - IDDA (PSC-2020-132)</td>
<td>$307,603,000</td>
</tr>
<tr>
<td>Coronavirus Response and Relief Supplemental Appropriations Act</td>
<td>$100,000,000</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$1,197,603,000</strong></td>
</tr>
</tbody>
</table>

**RADx Tech program now funded through FY 2021**

- NIBIB Base Budget FY20/21: $814,366,000
- NIBIB Supplemental Budget FY20/21: $1,197,600

**Goal:** Establish RADx as core NIBIB program for FY22+
Leadership Update

Francis Collins, M.D., Ph.D
Reappointed NIH Director

Science Appointments:
Eric Lander, PhD: OSTP Director and Presidential Science Advisor
Alondra Nelson, Ph.D.: OSTP Deputy Director for Science and Society
Frances H. Arnold, Ph.D., Co-Chair of the President’s Council of Advisors on Science and Technology
Maria Zuber, Ph.D., Co-Chair of the President’s Council of Advisors on Science and Technology
Funding Announcements & Opportunities

• NIH Katz Award
• NIH-NSF Smart and Connected Health
• HEAL Initiative
• NIH FIRST Award
• Music and Health
• Synthetic Biology
• DEBUT
• R21 Mechanism
New NIH Program: *Katz ESI R01*

- Investigator-initiated R01
- Early-Stage Investigators (ESI)
- No preliminary data allowed
- New research direction for PI
- Up to 5-years may be requested
- Two Katz FOAs:
  - PAR-21-038 (Clinical Trial Not Allowed)
  - PAR-21-039 (Basic Experimental Studies with Humans Required)
    - *NIBIB is not participating on PAR-21-039*

*First due date January 26, 2021*

NIH Katz Award Committee
Co-chair, David George, Ph.D.
Member, Randy King, Ph.D.

Katz Program website [https://grants.nih.gov/funding/katz-esi-r01.htm](https://grants.nih.gov/funding/katz-esi-r01.htm)
Successful NSF-NIH program since 2013; aligns with NIBIB programs/mission

**NOT-OD-21-011: Notice of NIH Participation in Smart Health and Biomedical Research in the Era of Artificial Intelligence and Advanced Data Science**

Developing technologies to transform health and medicine ($300K/year, up to 4 years)

The new program “Smart Health and Biomedical Research in the Era of Artificial Intelligence and Advanced Data Science”, was restructured to promote two goals of the NIH’s Strategic Plan for Data Science with 23 ICOs’ participation

**Application due date February 16, 2021**

Qi Duan, Ph.D.
Program Director
HEAL Initiative: HEALthy Brain & Child Development

Goal: understand impact of fetal drug exposure, adversities on mental & behavioral health; inform intervention/prevention strategies.

Longitudinal study: cognitive, psychosocial assessments + advanced imaging (MRI, EEG, NIRS etc.)
- 7,500 subjects to be scanned from birth to 10 years old.
- Portable imaging tech, e.g. EEG and fNIRS, for infants in motion, baby-caregiver interactions, etc.
- New imaging tech, e.g. novel fMRI and fetal ultrasound, in large-scale study.

Four FOAs:
- RFA-DA-21-020 - Unlinked Research Project Sites (U01)
- RFA-DA-21-021 - Linked Research Project Sites (U01)
- RFA-DA-21-022 - Consortium Administrative Core (U24)
- RFA-DA-21-023 - Data Coordinating Center (U24)

Letter of Intent: March 1st, 2021; Application: March 31st, 2021

Shumin Wang, Ph.D.
Program Director
Objective: Create cultures of inclusive excellence
Common Fund intends to commit $241 million over nine years

RFA-RM-20-022: FIRST Cohort (U54 Clinical Trial Optional)

FIRST Faculty Cohort awards:
- Hire a diverse cohort: early-stage research faculty w/multi-level mentoring, professional development.
- Effect systemic and sustainable institutional culture change: address bias, equity, mentoring, and work/life issues.

RFA-RM-20-023: FIRST Coordination & Evaluation Center (U24 Clinical Trial Not Allowed)

FIRST Coordination and Evaluation Center:
- Coordinate and facilitate: development of strategies with FIRST Cohort awardees
- Conduct a comprehensive evaluation: impact of FIRST program

Application Due Date: March 1, 2021

Webinar January 25, 2021, 2 - 4 pm EST.
Music and Health FOA

PAR-21-099: Music and Health: Understanding and Developing Music Medicine (R21 Clinical Trial Optional)

Goals:
• Increase understanding of how music affects the brain
• Develop evidence-based music interventions to enhance health or treat specific diseases and disorders.

NIBIB Topics of interest (not limited to):
• Development of non-invasive human imaging tools and technologies to probe music’s impact on the brain.
• Effects of music on the quantity of sedatives and/or analgesics as required during image-guided interventions and other minimally invasive procedures.

Guoying Liu, Ph.D.
Program Director
NOT-EB-20-017: Notice of Special Interest (NOSI) Synthetic Biology for Biomedical Applications

Goals of this Notice are to:
1. develop tools and technologies to control and reprogram biological systems.
2. apply synthetic biology approaches for the development of biomedical technologies.
3. increase the fundamental understanding of synthetic biology concepts as they relate to human health.
4. gain fundamental biological knowledge through the application of synthetic biology approaches.

The NOSI will fund R01, R21, and R35 research projects.

The NOSI expands the trans-NIH Synthetic Biology partnership from 3 ICs to 8 ICs

NOT-EB-20-022: Notice of Special Interest (NOSI) Administrative Supplement for Providing Travel Support for Awardees to Attend the Annual NIH Synthetic Biology Consortium Meeting (Admin Supp)
Design by Biomedical Undergraduate Teams Challenge

- Challenges **undergraduate teams** to design technology solutions for unmet health needs
- **Ideation** projects & projects with **Prototypes**
- Total of **$115,000** in Prizes!
  - **Submission Deadline:** June 1, 2021
  - **Winners Announced:** August 25, 2021
  - **Award Ceremony:** October 2021, BMES meeting

Visit https://www.nibib.nih.gov/research-programs/DEBUT-challenge

**NIBIB Prizes**
- The Steven H. Krosnick Prize: **$20,000**
  - Second Prize: **$15,000**
  - Third Prize: **$10,000**
- HIV/AIDS Prize: **$15,000**
- NIMHD Tech for Low-Resource Settings Prize: **$15,000**
- 5 Honorable Mentions: **$1,000** each

**VentureWell Prizes:**
- Venture Prize: **$15,000**
- Design Excellence Prize: **$5,000**
PAR-18-433: NIBIB Exploratory/Developmental Research Grant Program (R21 Clinical Trial Optional)

Key Features:
- No preliminary data allowed
- Balancing considerable risk with potential high impact research
- Expires May 8, 2021 (per issuance of NOT-EB-20-013)

NIBIB will be discontinuing this Exploratory/Developmental R21 FOA. Alternatives include:
- R03
- Short-term R01
- Katz R01
- NIBIB Trailblazer R21
Program Updates

- DS-I Africa
- BRAIN
- Diversity Working Group
- COVID-19
Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa)

Over 100 diverse group of applications received for the following FOA’s:
- Open Data Science Platform and Coordinating Center (ODSP/CC)
- Ethical, Legal and Social Implications of DS-I Research
- DS-I Research Training Program
- Research Hubs

Applications for ODSP/CC received from South Africa, Nigeria, Ghana, Uganda, Kenya, Sudan, Mali, Egypt, Tanzania, Mauritius and Rwanda

Timeline for FOA-RFA-RM-20-018

- Applications Due: December 3, 2020
- Scientific Merit Review: April/May 2021
- Advisory Council Review: August 2021
- Earliest Start Date: September 1, 2021

https://www.nibib.nih.gov/research-funding/data-science-initiative-dsi
BRAIN Initiative Workshops

Dissemination of Non-Invasive Imaging Technologies

- February 18-19, 2021
- Purpose: to feature progress updates from BRAIN Initiative awardees and presentations from industry on potential pathways for follow-on dissemination.
- Agenda and Speaker Information

Transformative Non-Invasive Imaging Technologies

- March 9-11, 2021
- Purpose: to bring together neuroscientists, tool developers/engineers, and industry partners to identify new non-invasive functional imaging tools that could be realized in the next five to ten years.
- Agenda and Speaker Information

Shumin Wang, Ph.D.
Program Director
Co-chair

George Zubal, Ph.D.
Program Director
BRAIN Initiative Workshops

Dissemination of Non-Invasive Imaging Technologies

- February 18-19, 2021
- Purpose: to feature progress updates from BRAIN Initiative awardees and presentations from industry on potential pathways for follow-on dissemination.
- Agenda and Speaker Information

Transformative Non-Invasive Imaging Technologies

Shumin Wang, Ph.D.
Program Director
Co-chair
Diversity, Equity and Inclusion: NIBIB Community

NIBIB Community:
• Intellectually Diverse and Embracing of New Ideas
• Problem Solvers: Blend Technology and Altruism
• Diversity Essential For Growth, Success

Co-Chairs of New Advisory Council Working Group

• Developing Diverse, Inclusive Workforce and Leadership
• Addressing Structural and Systemic Barriers, Bias
• Advancing Technology for Reducing Disparities, Improving Access
Diversity, Equity and Inclusion: *NIBIB Community*

**NIBIB Community:**
- Intellectually Diverse and Embracing of New Ideas
- Problem Solvers: Blend Technology and Altruism
- Diversity Essential For Growth, Success

- Special Council Working Group, Advisory to Director
- 5 Additional external invitations in progress
- Council member participation encouraged
- Become recognized leadership voice for NIBIB community
- Coordinate with NIH-wide efforts on Diversity (UNITE)

Gilda Barabino, Ph.D.  
Roderic Pettigrew, Ph.D., MD

Manu Platt, Ph.D. Associate Professor, BME, GaTech  
Greg Washington, Ph.D. President, George Mason University

Zeynep Erim, Ph.D.  
Training Division Director
Diversity, Equity and Inclusion: *NIH-wide activity*

**NIH-Wide Approach:**

*From December 11, 2020 Advisory Council to Director (ACD) Presentation*

- Create trans-NIH committees reporting to the NIH Steering Committee and reporting out to NIH Advisory Committee to the Director (ACD) to address 5 interrelated, but distinct, workstreams

- Understanding stakeholder experiences through listening and learning
- New research on health disparities/inequities
- Internal workforce
- Extramural research workforce
- Talking and communicating with our internal external stakeholders
COVID-19 Pandemic

Bioengineering

1) Imaging and AI
2) Digital Health Platforms
3) Diagnostic Test Technologies
COVID-19 Supplements: NIBIB Program

Strong response to 3 NOSIs issued 4/10 (~5 mos, now expired)

- 21 Awards
- $8,420,883

- 37 Awards
- $13,505,355 Total Cost
Accomplishments (~5 months)

- MIDRC management/advisory structure (23 institutions)
- Data infrastructure, harmonization, evaluation, security and privacy requirements and processes
- Data model & data elements to enable use in AI development
- Contractual agreements with institutions interested in contributing data
- First MIDRC investigators meeting held in December 2020
- Actively link with NCATS N3C (National COVID Cohort Collaboration) for accessing COVID clinical data
- Recent RSNA publication re COVID chest images released to the public (S. Simpson et al. Radiology: Cardiothoracic Imaging 2021, 2(2))

In Progress

- 11 institutions to donate data through RSNA (RICORD) and ACR (CIRR)
- 15,000+ cases being processed for MIDRC ingestion
- 10,000+ more cases being processed for donation
- First users/data contributors meeting being planned for March 2021

1,240 COVID imaging studies available for users.

Donate Data: https://www.midrc.org/donate
Access Data: https://data.midrc.org/
Digital Health Solutions for COVID-19

- SAFER-COVID became NIH’s official return-to-work app
- More than 150K people have used the tool to date (NIH and non-NIH)
- Activity risk calculator was featured on CNN (https://safercovid.org/myrisk)
- Tool is being configured to assist with at-home COVID-19 testing
Undiagnosed rate in younger participants (5.9%), Black/African American (14.2%), Hispanic (6.1%), and urban residents (5.3%)

CDC: Total cases as high as 8X*

Sadler data similar conclusions

~3 million total cases: actual >20M?

~24 million total cases, actual?

*Heather Reese, et al., Clinical Infectious Diseases, ciaa1780, https://doi.org/10.1093/cid/ciaa1780
RADx Tech & ATP Goals

1) Expand COVID-19 Testing Technologies: Number, Type and Access
2) Optimize Performance: Technologic and Operational; Match Community Needs

Test Settings
- Home-based
- Point of Care (POC)
- Laboratory (CLIA, research)

POC > Lab
+ >2 million/day LFA antigen tests unreported

Covid Tracking Project
RADx Tech/ATP Innovation Funnel

Applications Started
~3000

Projects in each Phase
716
137
47
25 (Tech + ATP) ~$500M

NATIONAL CALL FOR INNOVATIVE TECHNOLOGIES
PHASE 0: “Shark Tank”-Like Rapid Selection Process
PHASE 1: Validation and Risk Review
PHASE 2: Clinical Tests, Regulatory Approval, and Scaling Up
END OF SUMMER/FALL 2020

Rolling Submissions and Selections Begin April 28, 2020
5-6 Months

by end of year

DEPLOY MILLIONS of tests per week
Validation, Clinical Testing, Regulatory, Manufacturing, Distribution

National Institute of Biomedical Imaging and Bioengineering
Mesa BioTech
Visby Medical
Ubiquitome
Fluidigm
Luminostics
Flambeau
Maxim
Quidel Sophia
Yukon Swabs
AnP
Ellume
Ubiquitome
Quidel Sophia
Quidel QuickView
Luminostics
ANP
Ellume
ANP
Ubiquitome
Quidel Sophia
Quidel QuickView
Luminostics
ANP
Ellume

Point of Care & Home
Visby
Mesa
Microgem
Talis
MatMaCorp
Ubiquitome
Ellume
Quidel Sophia
Quidel QuickView
Luminostics
ANP
Ellume

Laboratory
Flambeau
Fluidigm
Broad Inst
Illumina
Helix
Gingko
Sonic Healthcare
PathGroup
Aegis
Quanterix

Lab Products
Mammoth Biosci
Ceres Nanosciences
Yukon

14 EUAs issued
### EUAs Issued

- **Mesa BioTech**
- **Visby Medical**
- **Ubiquitome**
- **Fluidigm**
- **Luminostics**
- **Flambeau**
- **Yukon Swabs**
- **ANP**
- **Ellume**

**Point of Care & Home**
- Visby: RT-PCR
- Mesa: RT-PCR
- Microgem: RT-PCR
- Talis: ISO-PCR
- MatMaCorp: RT-PCR
- Ubiquitome: RT-PCR
- Quidel Sophia: An-LFA
- Quidel QuickView: An-LFA
- Luminostics: An-LFA
- ANP: An-LFA
- Ellume: An-LFA

**Laboratory**
- Flambeau: PCR-mobile
- Fluidigm: RT-PCR
- Broad Inst: RT-PCR
- Illumina: NGS
- Helix: NGS/RT-PCR
- Gingko: NGS/RT-PCR
- Sonic Healthcare: RT-PCR
- PathGroup: RT-PCR
- Aegis: RT-PCR
- Quanterix: SIMOA (An)

**Lab Products**
- Mammoth Biosci: CRISPR
- Ceres Nanosciences: Beads/Conc
- Yukon Nanosciences: Swabs
RADx Leveraging NIH Proof of Concept (PoC) Network

~50 early-stage RADx-tech projects

Matt McMahon, PhD

Project Funding
Industry Coaching and Mentoring
Training and Resources
RADx Impact in 2020

- ~94 million capacity in 2020
- ~48 million sold in 2020
- ~950k tests/day produced
  Dec 2020; ~550k/day sold
- ~14 EUAs and 1st OTC EUA
- ~190 Companies supported

Feb 2021: Project millions OTC LFA tests/day

March 2021: Project >2.5M tests/day
Deployment Core: CIMIT/MGH (close gap)

Bridging NIH/USG, non-profit Foundations, Academia, and Industry

Nancy Gagliano, MD
CIMIT/MGH

“When-to-Test” modeling tool:
Match tests w/needs; evaluate impact of risk reducing activities.

https://whentotest.org/

Anette Hosoi
MIT

Paul Tessier,
CIMIT/MGH
Challenges: Screening/Surveillance LFA Performance

Wide Population Viral Loads ($n = 4774$)

Typical LOD $\sim 10^6$ Copies/mL
Sensitivity $\sim 40\%$ vs. RTPCR for all (symptomatic + asymptomatic)*

Vs.

Sens/Spec $\sim 90/95\%$ for symptomatic population (EUA: $\sim 5$ days post-onset)

Challenges: Screening/Surveillance LFA Performance

1) Use LFA within ~5-7 days of symptoms
   • Elevated viral load (>90% sens, spec)

2) “Off Label” LFA in Asymptomatics:
   • Backup PCR w/positive in low prevalence
   • Backup PCR w/negative recently exposed

3) Sequential LFA tests

Wide Population Viral Loads (n = 4774)

Ramy Arnaout, James E. Kirby, et al., SARS-CoV2 Testing: The Limit of Detection Matters bioRxiv 2020.06.02.131144; doi: https://doi.org/10.1101/2020.06.02.131144

M. Mina et al, NEJM, DOI: 10.1056/NEJMp2025631
**Mission:** Evaluate RADx platforms that advance to Phase 2 in rigorous clinical studies w/ diverse populations and settings.

- **Quidel Multisite study:** *UMass, UIUC, JHU in progress (n=200)*
  - Longitudinal sequential Lateral Flow Assay (LFA) assessment (2 weeks)
  - RTPCR, saliva, + viral infectiousness assay
- **LFA home testing study:** *UMass and Northwestern, Jan 25 (n=100)*
  - At home, Self sampling, Digital health platforms
- **LFA large population study, planning w/public health (n>200,000)*
  - Regular frequent tests break chain of transmission?
POC/Home Challenges: Digital Health

RADx POC Test

PCR

LFA

How to Use

Wearables

Symptom Surveys

Cell Phone Reader

e.g. OpenRDT (Audere)

Digital Contact Tracing

EHR & Claims

GATES foundation

Proof of Health Status

COVID-19 Pandemic

**Summary & Future**

Pandemic demands can’t be addressed by “off the shelf” solutions: *Be ready with new, purpose-driven tech.*

Bioengineers are multi-lingual integrators: *Urgent need to work closely with Public Health*

Leveraging existing networks by expanding is key for speed, impact: *Build in efficiencies to counter the natural growth of bureaucracy.*

Technology development relatively easy: *Adoption, guidance, modifying human behavior for surveillance & screening are hard.* **Partnerships, stakeholders!**

*RADx general platform for acceleration, impact: embedding in NIBIB structure, disseminating to NIH & beyond*
Thank You!
COVID19.nih.gov
NIH COVID-19 Website

✓ Get trusted, up-to-date, accurate information about NIH research.

✓ Learn about vaccines, treatments, and testing that are readily available.

✓ Find out how to join clinical trials and view resources from other federal agencies.