NIAID Update for Boston University
March 31, 2021

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National Institute of Allergy and Infectious Diseases
Topics

- NIAID Strategic Priorities
- COVID-19
- Budget Update
- Research Training Update
- Extramural Policy Update
- NIAID Funding Opportunities
NIAID Strategic Priorities for FY2021

- Maintain a robust portfolio of **basic and translational research** in microbiology, infectious diseases and immunology

- Accelerate research on SARS-CoV-2 and COVID-19 including:
  - Next-generation vaccines including universal coronavirus vaccines
  - Medical countermeasures
  - Post COVID-19 sequelae

- Develop **universal influenza vaccines** and enhance effectiveness of seasonal influenza vaccines

- Develop **medical countermeasures** for emerging and re-emerging infectious diseases

- Develop safe and effective **HIV vaccines** as well as **novel prevention, optimized treatment methods** and new approaches towards a **cure**

- Develop new strategies for the **prevention and treatment of immune-mediated** diseases with an emphasis on immune tolerance
In 2020, COVID-19 was the third leading cause of death in the U.S.*

PROVISIONAL 2020 DEATHS

1. Heart Disease 690K
2. All Cancers 598K
3. COVID-19 345K

COVID Update

- $1.5 billion of emergency appropriations under the FY20 Coronavirus Aid, Relief, and Economic Security (CARES) Act – most of these funds have been spent/obligated

- Over 2,000 R01 and R21 applications were received in response to NIAID’s COVID rapid response funding opportunity announcements in a 14-week period

- NIAID funds, along with funds provided under Operation Warp Speed ($1.27 billion to date), have funded the evaluation (through phase III clinical trials) of vaccines, therapeutics, and novel diagnostics
  - ACTT, ACTIV, and other clinical trials (ongoing)
  - Development and testing of animal models
Post-Acute Symptoms of COVID-19

- Post-acute symptoms of COVID-19 (PASC) can persist for months and can be debilitating
- The causes and risk factors associated with PASC are currently not known
- $1.15B in new funding to study PASC was included in the NIH FY21 appropriation
# The Next Big Challenge: COVID-19 Variants

## Vaccine efficacy or effectiveness (VE) against variants

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Study type</th>
<th>VE</th>
</tr>
</thead>
</table>
| Pfizer        | Post-licensure | • 86% in UK (predominate B.1.1.7 circulation)*  
|               |            | • 94% in Israel (up to 80% of cases from B.1.1.7) |
| Janssen       | Pre-licensure | • 74% in U.S.  
|               |            | • 66% in Brazil  
|               |            | • 52% in S.Africa |
| Novavax       | Pre-licensure | • 96% against non-B.1.1.7 in UK  
|               |            | • 86% against B.1.1.7 in UK  
|               | Pre-licensure | • 60% in S.Africa (93% of cases from B.1.351) |
| AstraZeneca   | Pre-licensure | • 84% against non-B.1.1.7 in UK  
|               |            | • 75% against B.1.1.7 in UK  
|               | Pre-licensure | • 10% against B.1.351 in South Africa |

As of February 2021
New COVID Funding Opportunities

- Emergency Awards: Notice of Special Interest (NOSI) on Pan-Coronavirus Vaccine Development Program Projects (NOT-AI-21-002) – next receipt date is June 11, 2021
- Protective Equipment Resources for COVID-19 Related Vaccine and Treatment Clinical Trials and Clinical Studies (S10, PAR-20-256) – rolling submissions through July 8, 2021
- Shared Personal Protective Equipment (PPE) Resources (S10, Clinical Trial Not Allowed) – not yet published, will expire in February 2022
Extensions for Early Career Scientists Whose Career Trajectories Have Been Significantly Impacted by COVID-19

**NOT-OD-21-052**: NIH is providing an opportunity for recipients of NIH Fellowship ("F") and NIH Career Development ("K") awards who have been impacted by COVID-19 to request budget extensions as follows:

- **No-Cost Extensions**
  - Recipients may extend the final budget period of the previously approved project period (e.g., no-cost extension) one time.

- **Funded Extensions**
  - Recipients, via the AOR, may request a funded extension for F and K awards by contacting the Grants Management and Program Official listed in the Notice of Award. These requests will be considered by each IC on a case-by-case basis depending on the availability of funds and adequate justification.
Flexibilities for Early Career Scientists Whose Career Trajectories Have Been Significantly Impacted by COVID-19

- **Administrative supplements** are available for young investigators impacted by COVID-19 so they can still meet their training and career development objectives.

- **Time extensions** (e.g., extended ESI status, extended NRSA payback period, time available for K22 and K99 grantees to obtain a faculty position) are also available to impacted investigators.

- Investigators who have been impacted should talk to their Program Officer about eligibility and available options.
Consolidated Appropriation Act, 2021

- FY 2021 omnibus and coronavirus relief bill signed on Dec. 17, 2020
  - $43 billion in annual funding for NIH
  - $1.25 billion for NIAID, a 3% increase
  - 6th consecutive year of substantial budget increases

- $1.25 billion in coronavirus funding available until Sept. 30, 2024
  - $1.15 billion – studies of long-term COVID-19 sequelae
  - $100 million – rapid acceleration of diagnostics (RAD-X)

- $40 million to be divided evenly among the 12 Regional Biocontainment Laboratories to support efforts to prevent, prepare for and respond to infectious disease outbreaks
NIAID Funding, 2000-2021

*Beginning in FY 2012, budget no longer passes through funds to the Global Fund.
## Budget Comparison by Institute/Center

<table>
<thead>
<tr>
<th>IC</th>
<th>FY 2020 Enacted</th>
<th>FY 2021 Enacted</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCI</td>
<td>$ 6,440,442</td>
<td>$ 6,559,852</td>
<td>1.9%</td>
</tr>
<tr>
<td>NIAID</td>
<td>5,885,470</td>
<td>6,069,619</td>
<td>3.1%</td>
</tr>
<tr>
<td>NHLBI</td>
<td>3,624,258</td>
<td>3,664,811</td>
<td>1.1%</td>
</tr>
<tr>
<td>NHGRI</td>
<td>606,349</td>
<td>615,780</td>
<td>1.6%</td>
</tr>
<tr>
<td>NCATS</td>
<td>832,888</td>
<td>855,421</td>
<td>2.7%</td>
</tr>
<tr>
<td>NIGMS</td>
<td>2,937,218</td>
<td>2,991,417</td>
<td>1.8%</td>
</tr>
<tr>
<td>NIA</td>
<td>3,543,673</td>
<td>3,899,227</td>
<td>10.0%</td>
</tr>
<tr>
<td>NIDA</td>
<td>1,462,016</td>
<td>1,479,660</td>
<td>1.2%</td>
</tr>
<tr>
<td>Other ICs</td>
<td>13,748,299</td>
<td>14,072,003</td>
<td>2.4%</td>
</tr>
<tr>
<td>Subtotal</td>
<td>$ 39,080,613</td>
<td>$ 40,207,790</td>
<td>2.9%</td>
</tr>
<tr>
<td>OD</td>
<td>2,409,387</td>
<td>2,532,710</td>
<td>5.1%</td>
</tr>
<tr>
<td>B&amp;F</td>
<td>200,000</td>
<td>200,000</td>
<td>0.0%</td>
</tr>
<tr>
<td>NIH Program Level*</td>
<td>$ 41,690,000</td>
<td>$ 42,940,500</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

*Includes Type I Diabetes and Non-HHS/Labor Appropriation (Superfund). Excludes OAR transfers.
NIAID FY 2021 Financial Management Plan

- Interim R01 payline
  - Established PI: **14th** percentile
  - New PI: **18th** percentile
- Interim R21 and R03 paylines: overall impact score of **31**
- Non-competing and competing grants: no adjustments
- Competing (solicited) research initiatives: cut up to 20%
- Estimated RPG success rate: 22-24%
Research Training Update

NIAID hosted a workshop with professional societies on research training in December 2019. Summary of recommendations has been published (J Infect Dis, 2020 Oct 13; 222(10): 1589-1591).
## Allocation of NIAID Training Budget

### FY2020 Training Budget

<table>
<thead>
<tr>
<th>Program</th>
<th>Awards</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ts*</td>
<td>176</td>
<td>$51M</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Success Rate = 56%</td>
</tr>
<tr>
<td>Fs</td>
<td>25</td>
<td>$11M</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SR = 13%</td>
</tr>
<tr>
<td>Ks</td>
<td>312</td>
<td>$47M</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Success Rate = 35%</td>
</tr>
<tr>
<td><strong>Total FY20</strong></td>
<td></td>
<td><strong>$109M</strong></td>
</tr>
</tbody>
</table>

* 56% of post-doc slots held by MDs and MD/PhDs

### Percentages

- Ts: 43%
- Fs: 10%
- Ks: 47%

- Percentages have been similar each FY over the past decade
- 1,355 trainees currently supported through K, F, and T awards
## NIAID’s K Mechanisms

<table>
<thead>
<tr>
<th>Category</th>
<th>Program</th>
<th>Candidate</th>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transition to Independence</td>
<td>K22</td>
<td>PhD, MD</td>
<td>No more than 5 yr as a Postdoc</td>
</tr>
<tr>
<td></td>
<td>K99/R00</td>
<td>PhD, MD</td>
<td>No more than 4 yr as a Postdoc</td>
</tr>
<tr>
<td></td>
<td>PS K99/R00</td>
<td>MD</td>
<td>Can be a non-citizen</td>
</tr>
<tr>
<td>Targeted Research</td>
<td>K01*</td>
<td>PhD, MD</td>
<td>Postdoc or Junior Faculty</td>
</tr>
<tr>
<td></td>
<td>K25^</td>
<td>PhD</td>
<td></td>
</tr>
</tbody>
</table>

- epidemiology, computational modeling, outcomes research; ^quantitative science, bio-engineering
- “MD” (above) includes MDs and MD/PHDs
NIAID’s K Mechanisms

<table>
<thead>
<tr>
<th>Category</th>
<th>Program</th>
<th>Candidate</th>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>K24*^</td>
<td>MD</td>
<td>Associate Professor</td>
</tr>
<tr>
<td></td>
<td>K23*</td>
<td>MD</td>
<td>Fellow or Junior Faculty</td>
</tr>
<tr>
<td></td>
<td>K08</td>
<td>MD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>R38</td>
<td>MD</td>
<td>Resident</td>
</tr>
<tr>
<td></td>
<td>K38#</td>
<td>MD</td>
<td>Fellow</td>
</tr>
</tbody>
</table>

- *patient oriented research required; ^K24 grantee mentors others, must hold R01 time of application; #open to participants who “graduated” from the R38 “Research in Residency” program
- “MD” (above) includes both MDs and MD/PhDs
The **Stephen I. Katz Early-Stage Investigator Research Project Grant** supports an innovative project that represents a change in research direction for an early-stage investigator (ESI) and for which no preliminary data exist.

Applications submitted to this Funding Opportunity Announcement (FOA) must not include preliminary data and applications must include a separate attachment describing the change in research direction.

Submission deadlines are: May 26, 2021; September 28, 2021; January 26, 2022; May 26, 2022; September 27, 2022; January 26, 2023; May 26, 2023; September 26, 2023.

These are 5-year R01 awards.
NIAID New Innovator Awards

- The NIAID New Innovators Award (DP2) supports a postdoctoral or newly independent Early-Stage Investigator of exceptional creativity who proposes novel, original and insightful research concepts with the potential for major impact in NIAID mission areas (PAR-20-259)

- The NIAID DP2 program is designed to facilitate the movement of exceptionally talented postdocs into independent positions and to support exceptionally talented investigators within the first year of an independent position

- Submission deadlines are October 14, 2021 and October 14, 2022

- These are 5-year DP2 awards (up to $300K in direct costs/yr)
Training and Career Development Opportunities

FY20
- NIH Administrative Supplements to Promote Research Continuity and Retention of NIH Mentored Career Development Award Recipients and Scholars (NOT-OD-20-054)
- Stimulating Access to Research in Residency Transition Scholar (StARRTS) (K38; RFA-HL-20-006)

FY21
- Mentored Career Development Program (K01) for Early Stage Investigators Using Nonhuman Primate Research Models (PAR-20-258)
- HIV/AIDS Scholars Using Nonhuman Primate (NHP) Models Program (K01; PAR-20-231)
Training and Career Development Opportunities

FY21 (cont.)

- Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00, PAR-19-343)
- Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Institutionally-Focused Research Education Award to Promote Diversity (UE5, PAR-19-342)
- NRSA Childcare Supplements (NOT-OD-21-074)

FY22

- Support of Research Excellence (SuRE, R16)
- Support for Research Excellence-First Independent Research Support and Transition (SuRE-First, R16)
- National Resource Center for the SuRE Program (U24)
Extramural Policy Update
Change in Scope

- Because of the pandemic, many investigators were impacted through reduced access to their laboratories and institutional resources.
- Early on, many investigators inquired as to whether they could work on COVID-related projects since those laboratories largely remained open (and it was a better option than not doing any research in the interim).
- If investigators wanted to use their own grant funds (salary and research funds), and if the proposed new research was different than their funded specific aims, then pre-approval was required – this requirement was NOT waived because of the pandemic.
- In most cases these requests were approved, but in some cases, approval needed to be granted retroactively (not good…).
Preliminary Data as Post-Submission Material During the Pandemic

- Preliminary data updates are accepted as post-submission material
  - Under all activity codes and only if the funding opportunity announcement allows preliminary data
  - One page is allowed for (1) single project applications and (2) each component of a multi-project application
  - NIH post-submission material policy (NOT-OD-19-083), including 30-day submission deadline, remains effective

Notice to Extend Eligibility for Submission of K22 and K99/R00 Applications

- **NOT-AI-20-067** NIAID will provide at least a 2-receipt cycle extension of eligibility for individuals whose were eligible to apply for the K22 PAR-16-434, under normal eligibility rules expiring between June/July 2020 and February/March 2021.

- **NOT-AI-20-068** NIAID will provide at least a 2-receipt cycle extension of eligibility for individuals whose were eligible to apply for the K99/R00 Parent PA-20-188 and Physician Scientist programs PA-20-210, under normal eligibility rules expiring between June/July 2020 and February/March 2021.

- Resubmissions that meet policy definition on **NOT-OD-18-197** for either of these awards are also eligible for this extension.
  - Applicants normally eligible to apply for the June/July 2021 receipt date will have a 1-receipt cycle (roughly 4 months) extension.
NIAID Funding Opportunities
NIAID Support for Physician Scientists

- NIAID’s Physician Scientist K99/R00 transition-to-independence program
- Physician Scientist K22 transition-to-independence grants
- StARR (R38) and StARRTS (K38) Research in Residency programs, which are NHLBI-led programs
- Dual degree NRSA Fellowship (F30) grants
- Training opportunities for physician scientists within NIAID national and global clinical research networks
New Opportunity to Promote Diversity

- NIAID Career Development for Advancing the Careers of a Diverse Research Workforce (R25, concept approved at Jan. 2021 Council)

- Purpose is to provide research training institutions with support for career development training of early career researchers from groups underrepresented biomedical research in NIAID-specific mission areas
  - Serve as a complement to ongoing research training education and provide added career development support to meet the needs of individuals pursuing careers in biomedical, behavioral, and clinical research

- Duration of Awards: 5 years

- Not yet published, receipt date expected to be summer 2021
The purpose of this funding opportunity announcement is to support research to define the mechanisms regulating the establishment, development and maintenance of immunity throughout childhood (from birth to less than 18 years of age), including the impact of pathogenic or commensal microbes or vaccination against infectious diseases, allergens or environmental pollutants on immune ontogeny and function

- RFA-AI-20-077, U01 ($500K/yr direct cost cap on budget)
- RFA-AI-20-078, U19 ($1M/yr direct cost cap on budget)
- Clinical trials not allowed
- Submission deadline: June 4, 2021
The main goal of these centers is to provide administrative and shared research support to foster and elevate multidisciplinary tuberculosis research and provide exceptional mentorship to New Investigators. TRACs will provide core facilities, services and mentoring opportunities to achieve the goals of the program.

- RFA-AI-21-001, P30 ($600K/yr direct cost cap on budget)
- Clinical trials not allowed
- NIAID intends to commit $5,000,000 in FY 2022 to fund up to 5 awards
- Submission deadline is June 15, 2021
Research on Bat Immunology

- The purpose of this Funding Opportunity Announcement is to support research to characterize cellular and molecular constituents of the bat immune system and to understand protective innate and adaptive immune mechanisms in bats
  - PAR-21-184, R21
  - Clinical trials not allowed
  - Non-domestic applicant entities and non-domestic components of U.S. applications are allowed
  - Projects that include possible exposure to biohazards, both known and unknown, must include a Biohazard Protection and Safety Plan
  - Submission deadlines are July 15, 2021 and March 15, 2022
The Tropical Medicine Research Centers (TMRCs) will support research endeavors to: develop novel diagnostic, prevention and therapeutic strategies adapted for the unique needs of low and middle-income countries; create and sustain in-country research capacity; stimulate scientific collaboration and global partnerships; provide opportunities for junior and early-stage investigators to conduct research on neglected tropical diseases; and facilitate sample sharing to support translational research to develop or evaluate new drugs, diagnostics, vaccines, therapeutics, and/or vector control strategies.

RFA-AI-21-004, U01 (clinical trials not allowed)

- Non-domestic applicant entities and non-domestic components of U.S. applications are allowed
- NIAID intends to commit $3.8M in FY 2022 to fund 4-6 awards ($500K cap)
- Submission deadline is June 18, 2021
Questions?