



## National Institutes of Health National Institute of Allergy and Infectious Diseases Office of AIDS Research

#### **Physician-Scientist Workforce**

COVID-19 has had a profound impact on the U.S. biomedical research workforce. IDSA appreciates NIH's the agency's commitment to research training and increased flexibility during the COVID-19 pandemic in terms of extended deadlines, flexible submissions for trainees and early stage investigators and the expansion of Early Stage Investigator (ESI) status for qualified researchers.

IDSA has long advocated for increased investment in the biomedical research workforce, including research training and diversity. Our 2018 *Journal of Infectious Diseases* article, <u>Policy</u> <u>Recommendations for Optimizing the Infectious Diseases Physician-Scientist Workforce</u>, outlines recommendations for enhancing education, training, compensation and mentorship for early career physician-scientists, as well as ways to improve federal research funding, crosssector collaboration and workforce diversity. We have also partnered with NIAID and multiple scientific societies to <u>discuss</u> institutional research training efforts and recommendations to address the ESI pipeline and look forward to continuing to align our priorities.

In a recent <u>NIH workforce survey</u>, more than half (52.9%) of respondents who conduct laboratory-based research agreed or strongly agreed that the pandemic would probably have a negative impact on their careers (compared to less than 38% of those conducting other types of research). Infectious diseases physician-scientists are ideally equipped to address many important topics with regard to COVID-19 and other impending infectious disease threats, and identifying and addressing vulnerabilities specific to these researchers is critical to combating the pandemic and advancing additional workforce support.

#### We recommend:

- Increasing, improving and supporting mentorship opportunities for early career physician-scientists, particularly for early stage investigators from underrepresented groups;
- Expanding funding to provide more developmental K awards, T32 awards, F32 awards and support for the K-to-R transition, as well as K24 awards in support of their mentorship;
- Expanding support for investigators who are caregivers;

• Requiring large, multi-project initiatives to include leadership roles and K-like awards for early stage investigators (e.g., the Antimicrobial Resistance Leadership Group, U grants, multicenter grants).

#### Inclusion, Diversity, Access and Equity

Underrepresented groups face disproportionate impacts from COVID-19, both as patients and investigators. Female professors have reported that their research productivity has been negatively impacted by COVID-19, and this decrease is likely for other <u>underrepresented</u> groups. Those hoping to make the K-to-R transition to research independence have reported a wide range of impediments, from laboratory closures to increased caregiving demands.

Beyond the research workforce, COVID-19 infection, hospitalization and mortality disproportionately affect individuals from underrepresented groups, including both racial/ethnic as well as socioeconomically disadvantaged groups. IDSA has authored a number of issue briefs to address COVID-19 and health disparities in the U.S., including for <u>immigrant</u> populations; <u>Black and African-American</u> communities; <u>Latinx</u> and <u>Native American</u> communities; and those in <u>correctional facilities</u>. We recommend data-driven and deliberate approaches to increase equity and support those who have been disproportionately impacted by COVID-19, as well as community-based strategies to increase diversity in clinical trials.

IDSA strongly supports NIH investment in Rapid Acceleration of Diagnostics — Underserved Populations RADx-UP to understand the factors associated with disparities in COVID-19 morbidity and mortality. We also applaud the agency's efforts to introduce a Challenge Prize in gender diversity and equity in higher education, as well as funding for community engagement research in areas hardest hit by COVID-19. Clinical trial engagement is a spectrum of activity from population health to recruitment, enrollment, engagement, retention and implementation, and IDSA stands ready to assist NIH and the U.S. Food and Drug Administration (FDA) in creating and fortifying opportunities for both investigators and participants. Further areas of research might include studying factors that underlie difficulties in enrolling underrepresented groups in clinical trials.

#### **COVID-19 Research Priorities**

IDSA applauds NIH for its swift and effective mobilization of research, partnerships and resources in a comprehensive effort to combat COVID-19.

In May 2020, IDSA outlined key <u>COVID-19 research questions</u> for NIH consideration that included the following recommendations:

• Develop common guidelines for research in outpatient settings and establish networks through which outpatient settings can collaborate on COVID-19 research. Research infrastructure is needed in these settings, and this is of particular importance with vaccines and new COVID-19 therapeutics in the outpatient space;

- Increase the grants available to early career infectious diseases investigators to attract necessary new talent to the field. Introduce grants in novel areas, such as social determinants of health and challenges to equity;
- Develop a multi-stakeholder partnership to address data/specimen collection and protocols for storage and analysis.

Additional recommendations include subject-area considerations for infection prevention, diagnostics, treatment, epidemiology, vaccines and translational research that seeks to understand impacts of social determinants of health on disease pathogenesis and therapy. We urge NIH to consider these additions to its <u>COVID-19 Strategic Plan</u>, as well as the additional questions of how COVID-19 specifically impacts children and the subsequent implications of disease transmission and spread. We appreciate the current plan's commitment to preventing and redressing COVID-19 health disparities and studying vulnerable populations, including pregnant women, newborns and incarcerated individuals. We also encourage clinical trial support for special populations like immunosuppressed patients and people with HIV for whom emerging data are starting to paint a less rosy picture than earlier in the pandemic. Among all HHS agencies, NIH is perhaps best equipped to study the wide range of COVID-19 manifestations and outcomes that remain central unexplained features of the pandemic.

#### NIH RADx Initiative

On September 2, NIH <u>announced</u> that it would be awarding scale-up and manufacturing support to test manufacturers under its Rapid Acceleration of Diagnostics (RADx) initiative, a program intended to support the development of innovative rapid SARS-CoV-2 tests. IDSA agrees with the key considerations for RADx support, including speed, cost, accessibility and technical performance. We encourage NIH to continue working with the Biomedical Advanced Research and Development Authority (BARDA), the Defense Advanced Research Projects Agency (DARPA) and other public-private stakeholder partners to continue advancing this critical research. We also recommend an increased focus on developing COVID-19 diagnostics that predict severe disease to enable early treatment, which is critical in respiratory virus infections.

#### Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

The uncertainties of the COVID-19 pandemic require public-private partnership to develop coordinated research strategies for prioritizing and speeding development of promising treatments and vaccines. For these reasons, IDSA strongly supports the ACTIV initiative and its four fast-track areas for opportunity. We particularly appreciate the clinical trial capacity working group's focus on different populations and disease stages, as well as the vaccines working group's efforts to harmonize efficacy trials and enable analysis of correlates of protection across different vaccines constructs. We are pleased that the ACTIV trial frameworks include parameters that promote a preferred endpoint approach and subsequent harmonization among outcomes, as well as a focus on critical research topics. We recommend ensuring there are sufficient resources to support clinical trial enrollment in institutions without clinical trial experience.

#### Antimicrobial Resistance (AMR)

The growing antimicrobial resistance crisis — exacerbated by widespread use of broadspectrum antibiotics in people with severe COVID-19 — threatens modern medical advances, including cancer chemotherapy, transplants and other surgeries and care of complex patients. Increased research to deepen our understanding of AMR and develop new tools to prevent, detect and treat infections caused by multidrug resistant pathogens must be a key component of our national approach to AMR. Progress has been made under the National Action Plan for Combating Antibiotic Resistant Bacteria (CARB), but we must redouble our efforts to keep pace with growing patient needs. As the threat of AMR increases, our antibiotic arsenal dwindles. Nearly all large pharmaceutical companies have abandoned antibiotic research and development (R&D), and the small companies responsible for the vast majority of recent innovation are struggling to stay in business. In 2019, two small antibiotics companies filed for bankruptcy, despite launching important new antibiotics.

#### We recommend:

- Increasing funding for AMR research;
- Streamlining bureaucratic processes for AMR research, including adopting practices employed with other clinical trials networks (such as the Pediatric Trials Network in the National Institute of Child Health and Human Development (NICHD) and the heart failure networks in the National Heart, Lung and Blood Institute (NHLBI)) to provide greater efficiencies for AMR research, including for the Antibacterial Resistance Leadership Group (ARLG);
- Prioritizing the discovery and development of new antibacterial agents and other novel treatments, including antibody-based therapies and phage therapies;
- Establishing a clinical trials network, built upon the foundation of ARLG and in collaboration with FDA and international partners, to leverage resources to study new and existing antibiotics efficiently in well-designed trials;
- Supporting further study and development of rapid diagnostic tests to guide more rapid pathogen-directed therapy and reduce overuse of broad-spectrum antibiotics;
- Studies to support the optimal use of antibiotics and inform strategies to reduce the overuse and misuse of antibiotics and advance antimicrobial stewardship.

# Office of AIDS Research (OAR)

As a multi-system, multi-organ disease, HIV is studied across the NIH centers and institutes, and OAR has played a critical role in coordinating HIV research across NIH since it was established by Congress in 1988. Similar to other areas of research, HIV research has been significantly affected by the coronavirus pandemic as many HIV researchers who are infectious diseases specialists have transitioned their research programs to conduct clinical trials to evaluate vaccines and therapeutics for COVID-19, and modifications in clinical practice have disrupted data sources for HIV-related studies. OAR will continue to play an important role in monitoring the impact of the coronavirus pandemic on HIV research and in aligning NIH's HIV research priorities with the goals of the National HIV/AIDS Strategy, the Ending the HIV Epidemic

initiative and the President's Emergency Plan for AIDS Relief (PEPFAR). Support for OAR's mission is more important than ever.

### Fogarty International Center

The NIH Fogarty International Center connects American scientists and health care professionals with their peers globally to support basic, clinical and applied research along with training programs in low-and middle-income countries. A bipartisan initiative, the center was created to promote international research and collaboration and has led to scientific advances contributing to improved health at home and globally. A vital part of the U.S. response to COVID-19 globally, the center quickly mobilized to respond to the pandemic, including providing technical assistance in low-and middle-income countries and conducting vital research on COVID-19 and its impacts, such as studying the intersection of COVID-19 and leading infectious disease killers such as HIV and tuberculosis.

The center sponsors over 500 research and health grants, with more than 100 of those related to the prevention, treatment and care of infectious diseases in areas of the greatest and most immediate need. Fogarty develops scientific expertise in resource-limited countries to detect and address pandemics where they begin. At the same time, all Fogarty grants involve U.S. investigators, and 80 percent go to U.S. institutions, building domestic knowledge and skills while improving global health. Fogarty will continue to be a vital program for combating COVID-19 and other infectious diseases globally while developing the next generation of American scientists and researchers and strengthening American health security. Since international travel has been integral to the Fogarty's research program, much of the work has been stalled by the pandemic.

#### We recommend:

- Supporting international research efforts until travel resumes;
- Increasing funding for the center to address the research and training needs associated with the COVID-19 pandemic and its impacts on other infectious disease areas in low- and middle-income countries;
- Prioritizing implementation science and research capacity in low-resource settings to strengthen the scale-up of evidence-based programming and practices to combat infectious diseases.

For questions regarding our recommendations, please contact Amanda Jezek, IDSA Senior Vice President for Public Policy and Government Relations at <u>ajezek@idsociety.org</u> or Andrea Weddle, HIVMA Executive Director at <u>aweddle@hivma.org</u>.