

FIRST VIRTUAL VERSION ACD Recounts Progress at a Tumultuous Time

BY RICH MCMANUS

Against a backdrop of national anguish over the death of George Floyd in police custody and a global coronavirus pandemic that by then had claimed more than 116,000 American lives, the 120th meeting of the advisory committee to the NIH director (ACD) held its first-ever virtual meeting June 11-12, tackling both NIH's response to the Covid-19 crisis and a variety of compelling administrative issues.

"As far as we can tell, this is the first time we've held [the ACD] in this format," observed Collins, who said he had only been



NIH director Dr. Francis Collins presides from his home office over the first-ever virtual meeting of the ACD.

on campus three times since the pandemic made telework mandatory for most staff, starting in mid-March. "I must admit it's a very unusual way to oversee the largest biomedical research organization in the world."

He began with "a huge shout-out" to the NIH staff's rapid response to the evolving

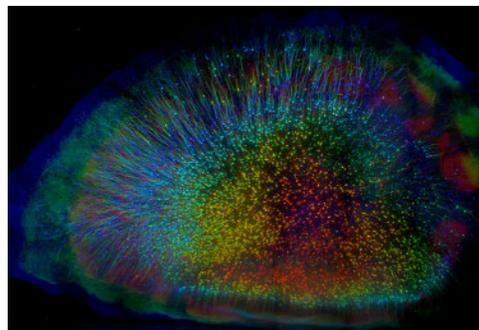
pandemic. "They are working 24/7 on a set of Covid-19 initiatives, while not neglecting NIH's other important priorities. Eighty to 100-hour weeks are routine...But I do really regret not being in the same room with you."

Addressing the gravity of the moment, Collins said there remains much work to do everywhere, including in biomedical research, to combat racism.

"We need to foster a more inclusive culture that generates equity and respect for one another," he said.

"We can rise to this occasion in new ways...Our diversity fuels our creativity and innovation. We too have been caught up in the grief, and the anger and distress, and I think we need to acknowledge that...We are not yet post-racial. The problem began, one might say, more than 400 years ago."

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Visit prize-winning "Cortical Forest" on p. 5

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'EPITOME OF SERVING' NIMHD's Tyus Returns from Pandemic Deployment

BY CARLA GARNETT



Dr. Nadra Tyus

March was her back-up on-call month, so NIMHD's Dr. Nadra Tyus, a commander in the Public Health Service Commissioned Corps, was hardly surprised when she was asked to deploy. She literally jumped into gear.

The Covid-19 pandemic was already well underway globally. Early in the month,

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Clear Goals, Objectives Key to Effective Science Communication

BY ERIC BOCK



Dr. John Besley

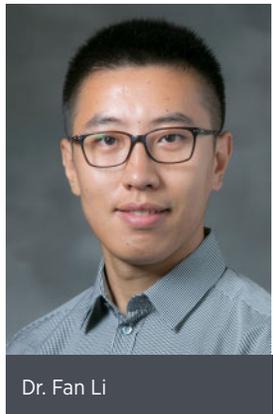
There's more to communicating scientific information to the public than translating complex information into plain language. Scientists must also think about what goals and objectives they want to achieve when they communicate,

said Dr. John Besley during a recent OBSSR Director's Webinar.

SEE BESLEY, PAGE 10

Webinar on ‘Stepped Wedge Trials’ July 14

The Office of Disease Prevention (ODP) will hold a Methods: Mind the Gap webinar with Dr. Fan Li on the overview of statistical models for the design and analysis of stepped wedge cluster randomized trials. The webinar will take place on Tuesday, July 14 at 1 p.m.



Dr. Fan Li

The stepped wedge cluster randomized design has received increasing attention in pragmatic clinical trials and implementation science research. The key feature of the design is the unidirectional crossover of clusters from the control to

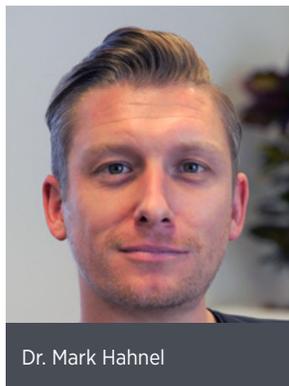
intervention conditions on a staggered schedule, which induces confounding of the intervention effect by time.

Li is an assistant professor of biostatistics at the department of biostatistics, Yale University School of Public Health. A biostatistician, he works with researchers from a variety of medical specialties in the design and analysis of cluster randomized trials, individually randomized clinical trials and observational studies.

Registration is required at prevention.nih.gov/education-training/methods-mind-gap/overview-statistical-models-design-and-analysis-stepped-wedge-cluster-randomized-trials. The webinar will be recorded and available on the ODP website within about a week.

ODSS Hosts Data Science Town Hall

The Office of Data Science Strategy will hold its next data science town hall on Thursday, July 23, from 12-1 p.m. All NIH employees and contractors interested in learning about NIH’s data science activities are invited to attend.



Dr. Mark Hahnel

The July town hall will feature guest speaker Dr. Mark Hahnel, founder and CEO of Figshare. NIH will conclude a 1-year pilot of Figshare on July 15, and ODSS has invited Hahnel to share his perspective on the pilot project, how

researchers can use generalist data repositories to better store and share their data and the future of data sharing. Hahnel founded Figshare, a generalist data repository, in 2012 and is an advocate for open



RADx Tech Featured in New NIBIB Video

NIH’s new Rapid Acceleration of Diagnostics initiative, or RADx Tech, aims to bring accurate, rapid and easy-to-use Covid-19 diagnostic tests to all Americans. The National Institute of Biomedical Imaging and Bioengineering recently released a video describing how the institute’s point-of-care network has mobilized engineers and innovators across the country to create different types of tests for use in a variety of settings and communities to help overcome this global crisis. To view the video, visit <https://www.youtube.com/watch?v=ofAIdSGoZOg>.

data and open research. He holds a Ph.D. in stem cell biology from Imperial College London.

To receive the Webex meeting invitation and other updates from ODSS, subscribe to the town hall listserv at <https://list.nih.gov/cgi-bin/wa.exe?SUBED1=datasci-ice&A=1>. Additional comments or questions should be emailed to ODSS at datascience@nih.gov.

Salzman Virology Award Nominations Due by Sept. 21

The Foundation for the National Institutes of Health, the NIH virology interest group and the Salzman organizing committee announce the 22nd annual Norman P. Salzman Memorial Awards and Symposium in Basic and Clinical Virology.

The awards have been established to recognize outstanding research in the field of basic and/or clinical virology at NIH, FDA, Fort Detrick Laboratories, Leidos, USDA or the Uniformed Services University of the Health Sciences. They honor the 40-year career of Dr. Norman P. Salzman in virology research and his accomplishments in mentoring of young scientists.

Starting this year, two awards will be given: the first to a postdoctoral fellow and the second to a graduate student/postbaccalaureate trainee. The winning

postdoctoral fellow will receive a plaque and an award of \$2,500. The winning graduate student/postbaccalaureate trainee will receive a plaque and an award of \$1,000.

The application due date is Sept. 21. Forms and information can be found at fnih.org/SalzmanSymposium. Applications must be submitted by email to SalzmanSymposium@mail.nih.gov.

The awards will be presented at a symposium being held virtually on Nov. 9. It will include prominent speakers in the field of virology, including: keynoter Dr. Rino Rappuoli, chief scientist and head, external R&D at GlaxoSmithKline; Dr. Jesse



Dr. Norman P. Salzman

Bloom of Fred Hutchinson Cancer Research Center; Dr. David Wang of Washington University School of Medicine in St. Louis; Dr. Richard Kuhn of Purdue University; and this year’s tribute speaker, Dr. Marshall Bloom, chief of NIAID’s Rocky Mountain Laboratories.

For more information, contact Dr. Nihal Altan-Bonnet (nihal.altan-bonnet@nih.gov) or Janelle Lewis (jlewis@fnih.org).

Individuals who need reasonable accommodation to participate in this virtual event should contact Lewis (301-594-3919) and/or the Federal

Relay (1-800-877-8339).

NIH'ers Volunteer on Frontlines of Covid-19

BY MEREDITH CARLSON DALY

Lola Saidkhodjaeva no longer fears Covid-19.

The global pandemic that has caused a national death toll of more than 125,000 has emboldened the young registered nurse. Soon after landing her first full-time nursing position in NICHD's intramural program, Saidkhodjaeva found herself unable to work from home since she could not interact with Clinical Center patients. The SARS-CoV-2 virus had shut down NIH and much of the country. Yet, Saidkhodjaeva, 26, knew the need was overwhelming for nurses across the country.



Lola Saidkhodjaeva

Her Clinical Center colleague Dr. Joseph Chinquee suggested they sign up as volunteers to support HHS missions during the pandemic. Chinquee, a volunteer paramedic in his home community of Mt. Airy, Md., and a doctor of health sciences, is the scientific and clinical manager of NCI's Laboratory of Pathology. He is also a seasoned volunteer, first with the Ebola outbreak in Liberia a few years ago, then in Puerto Rico helping with recovery efforts after Hurricane Maria. They both responded immediately when HHS put out the call.

Within hours, they were deployed to assist the Public Health Service in the Navajo Nation in New Mexico. During their



Dr. Joseph Chinquee

month-long experience, they have witnessed the Navajo Nation surpass New York state for the highest per capita SARS-CoV-2 infection rate in the United States.

The two first-generation immigrants say they have worked hard to get to NIH and wanted to give back.

"At the NIH, I've been given so many opportunities and rewards," Chinquee said. "I will never stop giving back, but I would not be able to volunteer for these missions without the full support of my NCI leadership."

Both Chinquee and Saidkhodjaeva said their supervisors and senior leaders were extremely supportive. Saidkhodjaeva is a research nurse specialist in the lab of Dr. Constantine Stratakis. Both Stratakis and Dr. Forbes Porter, NICHD clinical director, as well as Executive Officer Rodney Rivera, approved and signed paperwork on a weekend within hours, giving her the opportunity to deploy quickly.

Chinquee's branch chief, Dr. Kenneth Aldape, and NCI Executive Officer Donna Siegle approved his request within minutes of receiving the memorandum of understanding that allowed Chinquee to deploy with only 24 hours' notice.

They worked 12-hour night shifts at the Northern Navajo Medical Center on a medical-surgical floor converted to treat Covid-19 patients. During the day, they tried to respond to work emails and conference calls. Their volunteer duty ended June 10. They were quarantined for 2 weeks before being allowed to return to the Clinical Center.

In their last full week, they both assisted in the emergency department, triaging patients. They were also assigned to help in a makeshift tent outside, screening potential

Covid-19 patients.

"The most challenging part has been seeing families lose loved ones," Saidkhodjaeva said. As many families have multiple generations living together in tight quarters, numerous family members in the same house have fallen ill. Many homes do not have running water or electricity, which makes handwashing impractical.

The most rewarding part, she said, is the gratitude that families express continually, despite the trauma. "They're always saying thank you and telling us how much they appreciate what we do."

The unusual and exhausting stint also has given her renewed confidence.

"I'm not afraid anymore," Saidkhodjaeva said. "If NIH takes SARS-CoV-2 patients as part of a research study, I wouldn't hesitate to volunteer. This experience has made me realize that my clinical skills are pretty strong." **R**



ON THE COVER: *Chikungunya Virus*

IMAGE: NIH 3D PRINT EXCHANGE

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NIH National Institutes of Health
Turning Discovery Into Health

Tyus

CONTINUED FROM PAGE 1

widespread testing for the novel coronavirus had been approved in the U.S. and a national emergency had been declared.

By Mar. 20, Tyus and another PHS officer were working alongside county, state and other federal employees at the American Airlines Center in Dallas.

“I got the request on a Wednesday and I was out by Friday,” she said, explaining



Lt. Lia Jasperse (l) of the Indian Health Service and Cmdr. Tyus

the call she received to report for a PHS mission. “They quickly wanted to stand up community-based testing sites—what we call the CBTSs—to bring initial testing capabilities to critical locations across the country.”

One of 2 such facilities to open in Dallas, her CBTS operated 7 days a week, generally from 8 a.m. to 8 p.m. Her assignment lasted 23 days.

“We had a unique partnership there with the City of Dallas and Parkland Hospital, which actually did the swabbing,” Tyus explained. “So the Parkland nurses are the ones interacting with the patients who were there to get tested. It was just a phenomenal local, federal and hospital partnership. My primary role as site lead was to ensure data integrity and the overall integrity of the

operations per Radm. Erica Schwartz, the current deputy surgeon general. It was a really good opportunity to see the partnership between the federal government and the local and state officials during this mission.”

The deployment was also a change of pace Tyus relishes every now and again. By day, she’s a health scientist administrator—a program official supporting investigators who do health disparity work. Her portfolio focuses on social and behavioral research.

In contrast, her PHS role puts her in a variety of quickly developing, ever-evolving situations, weather conditions and geographic locations. Tyus also serves as the training lead for her Rapid Deployment Force team. Days on a mission can be exhausting, but also exhilarating.

“I’ve been on a rapid deployment team since 2012,” she said, “so I’ve had a fair amount of deployment experience. And we receive various types of training as public service officers. It really was a seamless kind of transition to be in that role.

“My first [deployment] was on a reservation with the Lakota Sioux Tribe,” she recalled. “I did that within 6 months of getting into the Commissioned Corps. And I’ve done a few hurricanes. I’ve done response and recovery missions with Hurricanes Harvey and Maria. I have at least 5 or 6 deployments under my belt. I love it.



In mid-March, a community-based testing site organizes.

I think it’s the epitome of serving your nation with sort of the public health approach. It’s also a chance to do something different from your day job, a definite change of pace. I have to say my current leadership at NIMHD have been so, so supportive.”

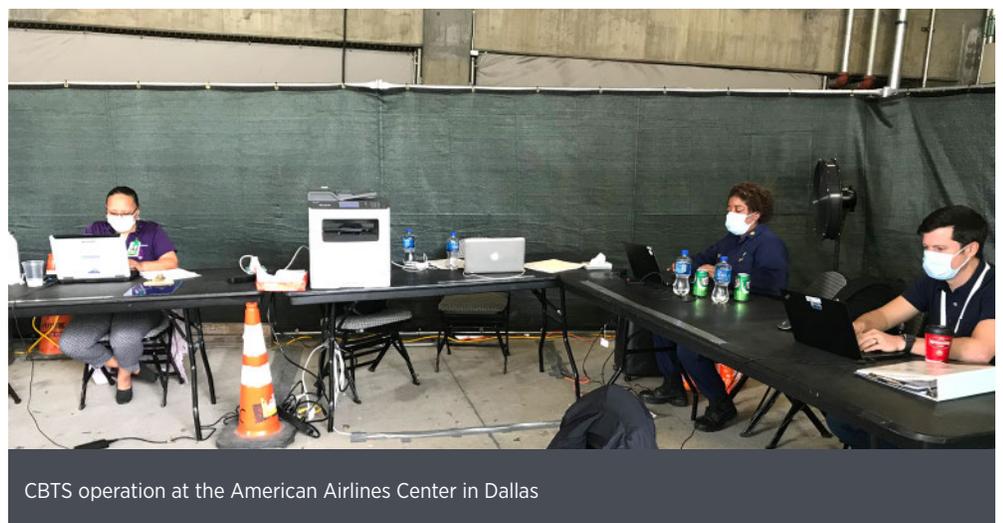
Tyus worked previously at a sister HHS agency, the Health Resources and Services Administration, for 9 years. She joined NIH last December.

Putting her most recent 3-week tour in perspective,

Tyus said she was very excited about the opportunity to work in the community. In fact, Covid-19 wasn’t even her first infectious disease epidemic. Not long ago, she was called up for an Ebola mission. For Tyus, it’s always the work that matters first and foremost.

“I’m used to the incident command structure, which is under [the Federal Emergency Management Agency], and I deployed to Liberia for Ebola,” she said. “So I’m used to the PPE [personal protective equipment]...Of course, the overall goals are different [for the two missions]. In Liberia, we were focused really on providing care to health care workers in the Ebola treatment unit. That was intense. And [Dallas] was a community-based testing site. So, I’ve had a lot of great experiences that really contributed to this role.”

Tyus’s deployment ended Apr. 11, and she was back to business as usual on Apr. 13.



CBTS operation at the American Airlines Center in Dallas

BRAIN Initiative Scientists Connect Virtually at 6th Annual Meeting

BY SHANNON E. GARNETT

Even the Covid-19 pandemic could not stop BRAIN Initiative scientists from connecting for their annual gathering this year. Instead of the usual in-person assembly, for the first time ever, the annual BRAIN Initiative investigators meeting took place as a 2-day virtual event, June 1-2.

Marking its sixth year, the meeting brought together the diverse groups supporting the U.S. BRAIN Initiative, including federally funded scientists, staff and leadership, as well as non-federal organizations, researchers interested in joining the BRAIN community and the public. The virtual conference was hosted on LabRoots—a scientific and educational social networking website—which provided an interactive forum for scientific discussions, plenary addresses and networking opportunities.

“Each year, I look forward to this meeting to learn about the great science being supported by the BRAIN Initiative, make new connections with other scientists in the field, meet with students, and, quite frankly, I just enjoy hanging out with my friends to talk about science and other things,” said newly appointed BRAIN Initiative director Dr. John Ngai. “The covid pandemic has deeply affected each of us as well as our communities and this has precluded us from having an in-person meeting this year. So while we work together to recover from this crisis, it is important for us to acknowledge and celebrate the many great discoveries that have been made over the last year and to imagine how



The 6th annual BRAIN investigators meeting took place as a 2-day virtual event that offered an interactive forum for scientific discussions, plenary addresses and networking opportunities. This screenshot provides a look at the virtual meeting space hosted on the LabRoots website.

we are going to use these discoveries to invent our scientific future.”

The meeting featured keynote lectures, trainee award highlight talks and symposium sessions covering various neuroscience topics—from electrode tool development and advances in neurotechnologies for human research, to model system diversity and connectomics capabilities. Also included was a neuroethics discussion on Covid-19 as well as workshops on narrative methods in science communication and correcting miscommunication and using social media to promote BRAIN science.

“The virtual forum brought together well over 4,000 BRAIN scientists, leadership and staff,” said Ngai. “It also welcomed the media and the public,

making it truly an open space for sharing the latest tools and discoveries in neuroscience research.”

In fact, more than 4,400 people registered for this first-ever cyber BRAIN meeting. On the first day, there were 2,571 unique visitors to the meeting page, which was more than 58 percent of those registered and an impressive feat according to LabRoots. Even more noteworthy was that most visitors (1,870) stayed on the site for over 2 hours and viewed more than 47,000 pieces of content.

The virtual experience also managed to embrace many aspects of the in-person meetings. Attendees were able to interact with speakers via live moderated Q&A sessions and with one another via chat boxes. People participated in public group chats on subjects like neuroethics and team science in the networking lounge. They also visited the online poster halls featuring more than 400 abstracts and explored federal and non-federal exhibitor booths.

Posters, exhibit materials, broadcasts and resources are available free of charge on-demand through May 2021 at <https://www.labroots.com/virtual-event/2020-6th-annual-brain-initiative-investigators-virtual-meeting>.

Winners of the 2020 Show Us Your BRAINS! Photo and Video Contest were announced on the second day. The contest—which demonstrates the creativity of BRAIN scientists—showcased cool, eye-catching image submissions from anyone engaged in the initiative, regardless of discipline, career stage or funding source.

The meeting’s program committee helped select the top 12 images and videos, which were posted online for public voting in the days leading up to the event. The winning top 3 photos and top 3 videos were announced on June 2.

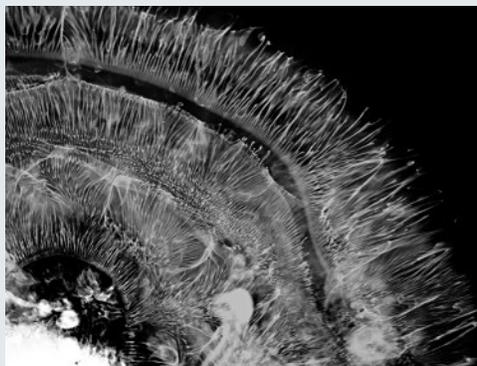
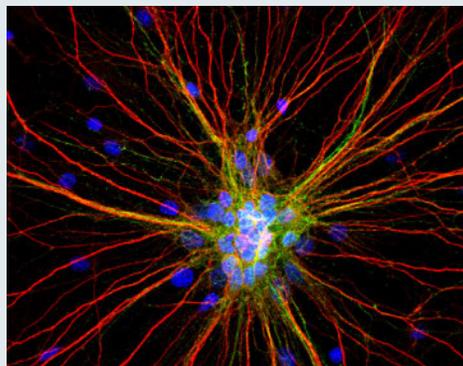
Photo contest winners are listed at left. To view all the winning images, visit <https://www.braininitiative.nih.gov/about/winners-2020-show-us-your-brain-contest>. 

‘Show Us Your BRAINS!’ Photo Winners

First Place: “Cortical Forest,” seen on page 1, is from Linus Manubens-Gil, South East University. Mouse Layer V cortical neurons eYFP-labeled (Thy1-H) and imaged after CLARITY processing of a whole brain. Maximum projection with depth color coding.

Second Place: “Radiating Neurons,” (below, l) from Karthik Krishnamurthy, Davide Trotti and Piera Pasinelli, Thomas Jefferson University. Four-week-old rat cortical neurons labeled for dendrites (red), axons (green) and nuclei (blue).

Third Place: “The Waterdrop Hippocampus,” (below, r) from Tallie Z. Baram, Jeremy Barry and Joan Morris, University California Irvine. “The brain is everywhere to us neuroscientists,” they said. “This exquisite hippocampus, with delicate dendrites, is actually a waterdrop captured at lightspeed.”





Roy Wilson, Wayne State Univer

ACD member Dr. M. Roy Wilson, president of Wayne State University, noted, “We really are in a very extraordinary time now of reckoning, with Covid-19, the murder of George Floyd... These have brought injustices into sharper focus...Racism is as urgent a public health matter as covid. One in 1,000 black men can expect to be killed by a policeman. I’ve had multiple encounters with the police in my lifetime that could have gone either way. Now, more than ever, we must seize the moment and not let up.”

ACD Meeting

CONTINUED FROM PAGE 1

Speaking via taped message, because he was at a White House meeting of the coronavirus task force, NIAID director Dr. Anthony Fauci gave an overview of NIH’s Covid-19 research response.

“The lives of all of us changed in late 2019,” he said. “This virus has essentially exploded on the world.” By June 11, there were some 7 million cases globally—more than 2 million in the U.S.—and more than 400,000 deaths worldwide. “For a while, the New York metropolitan area had half of the U.S. total [of deaths],” said Fauci.

A succession of speakers outlined the breadth of NIH’s response, including Collins, who noted that a public-private partnership



Dr. Shelley Berger (l) of the University of Pennsylvania warned PIs of being targeted by their former postdocs from foreign countries that may be seeking NIH’s intellectual property. NICHD director Dr. Diana Bianchi (r) began work on the MIS-C task force on Mother’s Day, when a *New York Times* article appeared describing the syndrome.



known as ACTIV—Accelerating Covid-19 Therapeutic Interventions and Vaccines—had launched on Apr. 17, just 2 weeks after initial discussions.

“This is unlike anything I’ve seen happen before,” said Collins. “It’s amazing how much can get done when people are not worrying about credit or money. Preventing suffering and death is more important.”

Also updating the ACD on ACTIV-related Covid-19 response were:

- Dr. John Mascola, director of the Vaccine Research Center, who said more than one vaccine is going to be needed to address the disease globally. “No one company could meet the need.” He said a series of phase 3 trials are set to begin in July, August and September. “We may have efficacy answers by the end of the year, if there are enough endpoints,” he said.
- NIAID clinical director Dr. Cliff Lane outlined three modes of inducing passive immunotherapy with antibodies, including convalescent plasma (87 studies as of June 6), hyperimmune immunoglobulin and mono-

clonal antibodies (at least 21 companies have products, some ready for phase 1 testing).

- NHLBI director Dr. Gary Gibbons discussed a major upcoming study of anticoagulants. “Seventy-one percent of patients who died of Covid-19 in China had systemic coagulopathy,” or blood clotting, he said. “While we’re all waiting for a vaccine, we need to manage this aspect.”

In addition to ACTIV, NIH



Lee

Dr. Brendan Lee of Baylor College of Medicine was one of the meeting’s most frequent commenters in the Zoom format of the virtual meeting.

has created the RADx (Rapid Acceleration of Diagnostics) Project, a \$1.5 billion effort involving 5 sub-projects, with the aim of greatly enhancing testing for the presence of the virus.

“A home-based technology would be revolutionary,” said NIBIB director Dr. Bruce Tromberg, who leads an effort that began only 7 weeks earlier. He anticipates a



“This is unlike anything I’ve seen happen before. It’s amazing how much can get done when people are not worrying about credit or money. Preventing suffering and death is more important.”

—NIH DIRECTOR DR. FRANCIS COLLINS



capacity to test 2 percent or more of the U.S. population daily by the end of the year.

Following its announcement just 5 days after funding from Congress, RADx attracted 400 applications in the first hour, 1,000 in the first week and 2,200 as of June 11, mostly from small businesses and academics, Tromberg noted.

Filling in RADx details were:

- Dr. Tara Schwetz, NIH associate deputy director, who discussed longer-term technology platforms to address future outbreaks of Covid-19 and other viruses. Even nationwide surveillance of wastewater is a possibility, she suggested.

• Dr. Rick Bright, who recently joined NIH from BARDA and is now senior advisor to Collins, described the Advanced Technology Program, which hopes to identify 3-5 technologies to meet RADx’s



As NIH broadly addresses the pandemic, ACD member Dr. Francis Cuss asked, “How do we assure the voice of the patient will be taken into account? I have heard it’s totally awful if you get hospitalized for Covid-19.”

ambitious daily testing goals by the end of 2020.

• NIMHD director Dr. Eliseo Pérez-Stable discussed the disproportionate burden of Covid-19 on racial and ethnic minorities in the U.S. and laid out the framework for a series of demonstration projects that would greatly enhance access to testing for these communities. “The distribution of this

pandemic is not equal across the country,” he said. “What factors contribute to these disparities?” A major goal is more testing. “We have the ability to do half a million tests per day now. We need 1 million per day.”

Collins has asked NICHD director Dr. Diana Bianchi and NHLBI’s Gibbons to co-chair a task force exploring the effects of Covid-19 on small children, some of whom end up with an illness similar to Kawasaki syndrome. Now known as Multisystem Inflammatory Syndrome in Children (MIS-C), the complication often presents with prolonged fever and inflammation. Severe gastrointestinal distress is common—some patients have been mistakenly diagnosed with appendicitis—as is shock and renal failure. Most patients improve with

treatment, but there have been a handful of deaths, said Bianchi.

Only a small percentage of youngsters get the full-blown syndrome, she noted, but 80 percent of those patients have cardiac involvement and risk of aneurysm and require long-term follow-up.

NICHD’s existing Pediatric Trials Network, consisting of more than 50 sites, will be used to study MIS-C, including a look at drugs not typically used in kids, Bianchi said. “We hope to study up to 10,000 at-risk children. We hope to learn more about Kawasaki syndrome, too—it’s been 50 years since it was first described, and we still don’t know the cause.”

Another existing NICHD network, the Maternal Fetal Medicines Unit, which can handle 21,000 pregnant women over 12 sites, will be tapped to study the impact of Covid-19 on pregnancy; there have been reports of placental abnormalities, Bianchi said.

On day 2 of the virtual meeting—each day was limited to about 3 hours (Collins joked that “Zoomness” can only be tolerated for so long) and began at 1 p.m. to accommodate West Coasters—several ACD working groups offered reports.



Dr. Michael Lauer, NIH deputy director for extramural research, acknowledged “a real hit in productivity for women with children” in the wake of Covid-19.

“NIH should use its unique position to set the tone to ensure that immediate and long-term changes are made to prevent sexual harassment,” said Dr. Carrie Wolinetz, NIH associate director for science policy and co-chair of the ACD working group on changing the culture to end sexual harassment.

It had been



Cal Tech’s Dr. Barbara Wold, echoing a concern of Lauer’s, said she is concerned about women with children at home during the pandemic whose research productivity has been altered.

thought at last December’s meeting that NIH lacked the statutory authority to discipline offenders at grantee institutions. But legal counsel, arguing on safety grounds, closed that loophole.

In 2019, 115 cases of sexual harassment were reported in the extramural community, Wolinetz reported. In the first half of 2020, 27 cases have been reported, resulting in the removal of at least 14 principal investigators from NIH-funded research.

Removals due to harassment have also occurred on NIH study sections and advisory councils—64 in 2019 and 20 so far this year.

Wolinetz said that equating sexual harassment with research misconduct is a new trend. But it is countered by another “worrisome trend—institutions acknowledge harassment, but don’t touch the person’s status or money...This supports the perception that institutions are protecting their rainmakers.”

“We were warned that this would happen,” said ACD member Dr. Francis Cuss, now retired from Bristol-Myers Squibb. “There may need to be more teeth involved in this.”

Said Collins, “We are going to continue to push forward on this—we are not done yet. Some thought that this was just talk, but we are serious. We are not going to tolerate harassment...and the grants process is where we have some clout. We intend to create an atmosphere that is fair and supportive. I promise you that’s what we will do.”

Updating the ACD on the issue of improper foreign influence, which first arose two summers ago, Dr. Michael Lauer, NIH deputy director for extramural research, first cautioned that the issue is “not a problem



Dr. Carrie Wolinetz (l), NIH associate director for science policy and acting chief of staff, said NIH can set the tone to ensure a harassment-free work environment. Dr. Roberta Brinton (r) of the University of Arizona noted that about 2 percent of the population are scientists, and wondered, “Can NIH interact with the Department of Education to [nurture] young, inner-city scientific geniuses?”



of collaboration, which is essential. Only a small percentage of people are involved...We must not create a climate that is unwelcome [to foreign scientists].”

At the moment, 359 “scientists of concern” have been identified at 87 institutions that have reached out to NIH in response to an awareness campaign launched by the Office of Extramural Research late last year, Lauer reported; so far, 189 NIH-funded researchers have been examined, 77 of whom were later removed from NIH support by their institutions.

In more than 90 percent of cases, China was the country of foreign support, Lauer said. China has more than 200 “talents” programs that aggressively seek intellectual property, he explained. “It is estimated that 15 percent of China’s GDP is devoted to science and engineering [talents] programs.”

Most of those removed were middle-aged Asian males holding a total of 285 grants, 76 percent of which was basic (mostly animal research), totaling \$164 million in NIH funding, Lauer noted.

He warned, “The numbers are not leveling off. I don’t know what the extent of the problem is. It may take many more months to figure this out.”

Updating the ACD on the activities of the working group on enhancing reproducibility and rigor in animal research, group co-chair Dr. Barbara Wold of Cal Tech said, “Animal experiments often serve as the foundation for human clinical trials. Thus, there is a cost when translatability fails.”



Collins mentioned that more than 2,700 NIH’ers have been tested for Covid-19 at the campus drive-through facility, and 214 have tested positive. “Almost all of them have done well,” he noted.



“Science itself has to do its own soul-searching [in the face of social injustice],” said Dr. Hannah Valantine, NIH’s chief officer for scientific workforce diversity.

She added, “We must avoid a black-and-white binary approach to reproducibility, especially when judging whether two results are ‘consistent’ or ‘the same’...It is important to recognize the interdependencies of rigor, transparency and reproducibility. No one alone ensures translatability to humans.”

Dr. Hannah Valantine, NIH’s chief officer for scientific workforce diversity (SWD), who leads the working group on diversity, gave the meeting’s final report. Ironically, her group had just met on June 10 to reflect on the impact of social injustice on scientific workforce diversity.

“We must openly acknowledge the problem of being black in science,” she said. “This is the moment to do something about this issue. People are really suffering. Science itself has to do its own soul-searching.” In times of stress, she warned, “We expect that the incidence of incivility and harassment will get worse.”

Like NIMHD’s Pérez-Stable, she acknowledged “the disproportionate impact of Covid-19 on the black community, especially women and other underrepresented groups... This is a time of emotional turmoil and feelings of hopelessness.” She argued, “When we uncover acts of racial bias, we should hold the perpetrators accountable, as we do with sexual harassment.”

Valantine’s office is preparing an SWD strategic plan for 2021-2025 and a

white paper on individuals with disabilities. They are also developing e-learning training on implicit bias that may eventually be mandatory.

In July, Valantine expects to launch an internal workforce survey of NIH’ers and plans to survey the extramural community in the future.

In other news at the biannual session, members learned:

- NIH’s budget for FY 2020 is \$41.7 billion, an increase of \$2.5 billion, or 6.4 percent, said Neil Shapiro, NIH associate director for budget. “All but 5 percent [of NIH’s purchasing power] has been restored since FY 2003, in inflation-adjusted dollars,” he said. The 2020 appropriation includes funds for a new surgery, radiology and laboratory medicine wing at the Clinical Center. Four supplemental bills to support Covid-19 research total \$3.6 billion, noted Shapiro. The President’s FY 2021 budget request for

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“We must openly recognize the problem of being black in science.”

-DR. HANNAH VALANTINE

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NIH is \$39 billion, which is \$3 billion less, or 6.1 percent, than 2020.

- There are 357 Covid-19-related projects involving 250 principal investigators ongoing in the Intramural Research Program, said Dr. Michael Gottesman, NIH deputy director for intramural research. The Clinical Center had reduced its bed census to 60 for critically ill patients during the onset of the pandemic, but is increasing to 90-100 beds, he added. “We’ll be able to test everyone at NIH in the not-too-distant future.” Capacity has increased from 1,000 tests per day to 10,000 per day with the addition of two new high-throughput instruments, Gottesman reported.

Collins said it is almost certain that the December ACD meeting will also be virtual, “unless something really amazing happens.”

To view the June sessions, visit <https://videocast.nih.gov/watch=37816> (day 1) and <https://videocast.nih.gov/watch=37820> (day2). **R**

Hydroxychloroquine Treatment Does No Harm, but Provides No Benefit

A clinical trial to evaluate the safety and effectiveness of hydroxychloroquine for the treatment of adults hospitalized with coronavirus disease 2019 (Covid-19) has been stopped by NIH.

A data and safety monitoring board (DSMB) met June 19 and determined that while there was no harm, the study drug was very unlikely to be beneficial to hospitalized patients with Covid-19. After its fourth interim analysis, the DSMB, which regularly monitors the trial, recommended to NHLBI to stop the study. NHLBI halted the trial immediately.

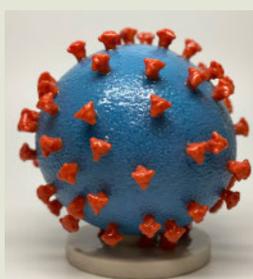
The Outcomes Related to Covid-19 treated with Hydroxychloroquine among In-patients with symptomatic Disease, or ORCHID study, was being conducted by the Prevention and Early Treatment of Acute Lung Injury (PETAL) Clinical Trials Network of NHLBI.

The data from this study indicate that this drug provided no additional benefit compared to placebo control for the treatment of Covid-19 in hospitalized patients.

The first participants enrolled in the trial in April at Vanderbilt University Medical Center, one of dozens of centers in the PETAL Network. The blinded, placebo-controlled randomized clinical trial aimed to enroll more than 500 adults who are currently hospitalized with Covid-19 or in an emergency department with anticipated hospitalization. More than 470 were enrolled at the time of the study's closure.

All participants in the study received clinical care as indicated for their condition. Those randomized to the experimental intervention had also received hydroxychloroquine. Participants in the study will now continue to receive standard care and follow-up as indicated for their condition.

ORCHID participants had been randomly assigned to receive hydroxychloroquine 400 mg twice daily for 2 doses (day one), then 200 mg twice daily for the subsequent 8 doses (days 2 to 5) or a placebo twice daily for 5 days.



3-D print of a SARS-CoV-2 virus particle. A clinical trial evaluating a potential treatment for the disease caused by the virus was recently halted.

IMAGE: NIH



Combining more healthy lifestyle behaviors was associated with substantially lower risk for Alzheimer's disease, according to a study funded by NIA.

Combination of Healthy Lifestyle Traits May Reduce Alzheimer's Risk

Combining more healthy lifestyle behaviors was associated with substantially lower risk for Alzheimer's disease in a study that included data from nearly 3,000 research participants. Those who adhered to 4 or all of the 5 specified healthy behaviors were found to have a 60 percent lower risk of Alzheimer's. The behaviors were physical activity, not smoking, light-to-moderate alcohol consumption, a high-quality diet and cognitive activities.

Funded by NIA, the research was published in the June 17 online issue of *Neurology*, the medical journal of the American Academy of Neurology.

"This observational study provides more evidence on how a combination of modifiable behaviors may mitigate Alzheimer's disease risk," said NIA director Dr. Richard Hodes. "The findings strengthen the association between healthy behaviors and lower risk and add to the basis for controlled clinical trials to directly test the ability of interventions to slow or prevent development of Alzheimer's disease."

The research team reviewed data from two NIA-funded longitudinal study populations: The Chicago Health and Aging Project (CHAP) and the Memory and Aging Project (MAP). They selected participants from those studies who had data available on their diet, lifestyle factors, genetics and clinical assessments for Alzheimer's disease. The resulting data pool included 1,845 participants from CHAP and 920 from MAP.

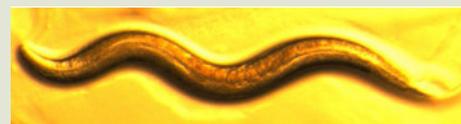
Gut Bacteria May Modify Behavior in Worms, Influencing Eating Habits

Gut bacteria are tiny but may play an outsized role not only in the host animal's digestive health, but in the animal's overall well-being. According

to a new study in *Nature*, specific gut bacteria in the worm may modify the animal's behavior, directing its eating decisions. The research was funded in part by NIH.

"We keep finding surprising roles for gut bacteria that go beyond the stomach," said Dr. Robert Riddle, program director at NINDS, which supported the study. "Here, the gut bacteria are influencing how the animal senses its environment and causing it to move toward an external source of the same bacteria. The gut bacteria are literally making their species tastier to the animal."

Researchers at Brandeis University, led by Dr. Michael O'Donnell, postdoctoral fellow and first author of the paper, and Dr. Piali Sengupta, professor of biology and senior author of the study, were interested in seeing whether it was possible for gut bacteria to control a host animal's behavior. The group investigated the effects of gut bacteria on how worms, called *C. elegans*, sniff out and choose their next meal.



C. elegans, 5 days old

IMAGE: COLEEN MURPHY, PRINCETON UNIVERSITY

Bacteria are the worms' primary food. In this study, the researchers measured how worms fed different strains of bacteria reacted to octanol, a large alcohol molecule secreted by some bacteria, which worms normally avoid when it is present at high concentrations.

O'Donnell and colleagues discovered that worms grown on *Providencia alcalifaciens* (JUb39) were less likely to avoid octanol compared to animals grown on other bacteria. Curiously, they found that live JUb39 bacteria were present in the gut of the worms that moved toward octanol, suggesting that the behavior may be determined in part by a substance produced by these bacteria.

Next, the researchers wanted to know how the bacteria exerted control over the worms.

"We were able to connect the dots, all the way from microbe to behavior, and determine the entire pathway that could be involved in this process," said O'Donnell.

Besley

CONTINUED FROM PAGE 1

“Science communication isn’t science education,” explained Besley, Ellis N. Brandt professor of public relations at Michigan State University.

Most scientists are open to communicating with the public about their research. Besley’s research has found that scientists often have short-term objectives when they communicate their work. For instance, they want to get people interested in their material or they want to teach their subject matter to the public.

However, Besley has found it difficult to get scientists to specify what else they would like to gain over the long-term from the time and effort they put into communication. Do they, for instance, want to change individual behaviors, such as getting people to drink



“Objectives are the ingredients of communication.”

—DR. JOHN BESLEY



less, quit smoking and exercise more? Or do they want to build public support?

Interestingly, Besley’s research has shown that scientists—when pushed—will say what they hope to achieve when they discuss their work. For example, they say they communicate to encourage policy makers to use scientific evidence, influence individuals’ behavior and inspire students to pursue a scientific career.

When scientists are trained in science communication, they often receive instruction about tactics such as speaking more clearly, avoiding jargon, fostering dialogue or telling stories. Scientists “are super willing” to prioritize different tactics, he said. Most are not willing to use negative tactics like purposefully making people angry. Tactics, however, are effective only “if they help you achieve your goals and objectives.”

According to Besley, “Objectives are the ingredients of communication.” Examples of objectives are trust-related beliefs about competence, integrity, motivation, openness and shared identity. Other objectives include beliefs about risks and benefits, social norms



“Science communication isn’t science education,” Besley said.

PHOTOS: MICHIGAN STATE UNIVERSITY

and self-efficacy. Affecting how others frame and feel about issues is also sometimes important. These are the building blocks scientists can use to meet their big-picture goals.

“If we’re doing strategy, we start with our goals. Then, we figure out which objectives let us achieve those goals. Finally, we pick tactics that let us achieve those objectives,” he said.

Many scientist-communicators aren’t aware of the need for clear objectives or rely on the most obvious ones such as knowledge and interest. Besley said they are willing to consider a broader range of objectives when they believe they will be effective and ethical. Clear objectives also allow researchers to evaluate why some tactics work in certain contexts and others don’t.

Once scientists prioritize objectives, they seem to be able to have better conversations about what to prioritize when communicating. For example, if a scientist has only an hour to speak to a group, he or she can think about tactics that will increase the odds the talk is successful. Researchers who wish to be perceived as being open to new ideas can come early or stay late, plan time for discussion and participate in question-and-answer sessions.

“Good communication is hard,” Besley concluded. It requires scientists to devote time and resources to the effort. “If we want to do it effectively, we need to pay for it.” **R**

NCI’s Hoover Retires, Leaving Legacy of Epidemiology Research

In June, Dr. Robert N. Hoover, director of the Epidemiology and Biostatistics Program, retired from the Division of Cancer Epidemiology and Genetics (DCEG) after 48 years of service to the National Cancer Institute.

He is widely known as an international leader in cancer epidemiology and expert in hormonal carcinogenesis, a visionary scientist who established multiple ongoing programs of research to understand the causes of cancer in human populations, as well as a generous mentor of scores of trainees.



Dr. Robert Hoover

Through his years of leadership at NCI, Hoover and Dr. Joseph Fraumeni, Jr., DCEG founding director and scientist emeritus, nurtured what began as a small branch into a large and diverse division that is recognized worldwide as the premier research program in cancer epidemiology. “From the beginning, Bob has been the quarterback of the epidemiology program at the NCI, serving as the driving force of the division with his dedication to uncovering the genetic and environmental causes of cancer,” said Fraumeni.

Hoover earned his B.A. from the University of Notre Dame, his M.D. from Loyola University in Chicago, and his Sc.D. in epidemiology from Harvard School of Public Health. He joined the Epidemiology Branch at NCI in 1972 as a commissioned officer in the Public Health Service. After holding a series of leadership positions, Hoover became director of the Epidemiology and Biostatistics Program when DCEG was founded in 1996.

Throughout his years of leadership, he has been particularly adept at building high-quality study resources not only for his own research, but also for the entire program through diverse collaborations across NCI and extramural organizations.

“Although population scientists recognize Bob’s tremendous life-long contributions to cancer epidemiology, what is often underappreciated are the myriad and unique ways that Bob facilitated many of the most challenging and essential advances in cancer research from behind the scenes,” said Dr. Robert T. Croyle, director of the Division of Cancer Control and Population Sciences. “He epitomizes science for the public good, with his intellectual generosity, wisdom and a remarkable ability to navigate political and bureaucratic barriers to collaboration, scientific progress and the application of rigorous evidence to public health. As a role model, mentor, investigator and colleague, he is second to none.”

Hoover was the first to utilize the entire SEER

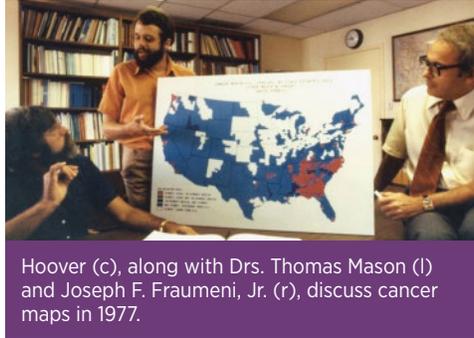
Cancer Registry Program as a resource for large population-based case-control studies of cancer and was among the first to collaborate with health maintenance organizations to access their medical records as powerful resources for prospective studies of cancer. In the early 1990s, he worked closely with NCI's Division of Cancer Prevention to develop the Prostate, Lung, Colorectal and Ovary Cancer Screening Trial (PLCO) into a powerful prospective observational study of all cancer sites. Its signature and unique serial collection of biospecimens and questionnaire data provided unprecedented potential for etiologic studies and the identification of biomarkers and remains a treasured resource still heavily utilized today.

In the last 10 years, Hoover has focused on developing a new “cohort of the future,” which will soon be realized through the Connect for Cancer Prevention Study. It will feature many of the same critical design elements that are the hallmark of his visionary planning: collection of serial information and biospecimens and utilization of electronic medical records to support cutting-edge molecular epidemiology over the next several decades.

A continuing focus of his personal research, which stemmed from his thesis work, has been understanding the relationship between hormones and cancer. Some of Hoover's contributions include the first study to identify menopausal hormone therapy as a cause of breast cancer, as well as the first to observe and establish the stronger carcinogenic effect of the combined estrogen-progestin regimen, compared with estrogen alone. These early studies were paradigm shifting, overturning then-conventional beliefs that hormones were protective against cancer.

In addition, Hoover pioneered research into the adverse effects of early-life hormonal exposures, most notably studies on women and their offspring who were exposed to diethylstilbestrol (DES). Between the early 1940s to 1970s, the first synthetic estrogen, DES, was marketed and prescribed to millions of pregnant women to prevent miscarriage and other complications of pregnancy. The association between prenatal DES exposure and vaginal and cervical cancer was established in the early 1970s and use was subsequently discontinued. However, by the late 1980s, most of the follow-up studies had progressively waned. Recognizing the need to continue observing DES-exposed mothers and their offspring, Hoover reached out to investigators at various study centers and successfully revitalized the cohorts, pooling the data to better answer the many questions that remained.

In 1992, the combined studies were assembled and named the DES Follow-up Study, the first and only large cohort of women and offspring exposed *in utero* to DES. To date the study has identified 12 major adverse health outcomes in addition to vaginal cancer and is continuing follow-up work on the third generation. The DES experiment—tragic for the affected families—benefited millions by demonstrating the urgent need for post-market monitoring of prescription medications.



Hoover (c), along with Drs. Thomas Mason (l) and Joseph F. Fraumeni, Jr. (r), discuss cancer maps in 1977.

His interest extended to other classes of treatments as well. He conducted the first epidemiologic assessment of cancer risks associated with immunosuppressive therapy and developed a systematic series of studies of carcinogenic risks associated with various cancer therapies. These studies altered our understanding of carcinogenesis as well as leading to changes in treatment strategies.

Another central theme of Hoover's research was development of the Cancer Atlas in 1975, which mapped mortality rates within the U.S. and internationally. While prior efforts generated only state-level mortality data, Hoover and colleagues produced county-level data that identified “hot spots” of cancer mortality—an early example of the promise of data visualization in epidemiologic research. Resultant case-control studies exploring these patterns linked lung cancer among men on the southeast Atlantic coast to their work in shipyards, and oral cancer risk among women in North Carolina to chewing tobacco. Recently, Hoover and colleagues used the same approach to connect arsenic in drinking water to the increased risk of bladder cancer in men and women in northern New England. His work has extended to other occupational and environmental exposures such as studies on groups exposed to pesticides, formaldehyde, arsenic and other agents, frequently producing findings leading to regulatory actions.

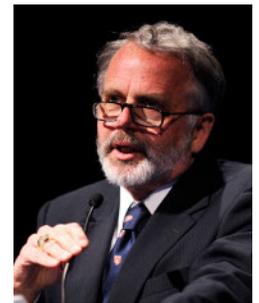
One of the pillars of Hoover's career was his dedication to mentorship. “Aside from his exceptional talent as a scientist, he is a tremendous and generous mentor whose wisdom was sought by all—from trainees, investigators, to branch chiefs and division directors, myself included—who lined up outside his office eagerly seeking his advice,” remarked Fraumeni.

“People sought out Dr. Hoover's advice for his epidemiologic rigor and breadth of knowledge, as well as his considerate and Socratic mentoring style of asking poignant questions to help trainees work through their challenges,” said Dr. Patricia Hartge, scientist emerita and former deputy director of the Epidemiology and Biostatistics Program.

Hoover has enjoyed mentoring two generations of junior investigators who have gone on to successful careers in government, academia and industry. He was recognized in 2015 by the NCI women scientist advisors with their Mentoring and Leadership Award for his exceptional dedication, leadership and tireless efforts to promote, nurture and mentor NCI women scientists at all stages of their careers.

Over the course of his career, Hoover has served NIH and the epidemiological community by providing expert assessments of epidemiologic evidence, evaluating plans and progress of scientific endeavors, sitting on search committees and advising on training programs. He has often been called upon by NCI and NIH to brief members of Congress and their staff on issues related to cancer epidemiology and science policy. He has been an advisor to many other government entities including the Food and Drug Administration, the Office of Management and Budget, the U.S. Military Cancer Institute and the Public Health Service. He has also lent his expertise to many national and international organizations including the World Health Organization, the International Agency for Research on Cancer, Union for International Cancer Control, the Danish Cancer Registry, the American Cancer Society, the General Motors Cancer Research Foundation and DES Action USA.

Hoover has received numerous honors, including the Distinguished Service Medal from the Public Health Service (1990), the Gorgas Medal from the Association of Military Surgeons of the United States (1996), the John Snow Award for Epidemiology Research from the American Public Health Association (2001), Alumni Award of Merit from the Harvard T.H. Chan School of Public Health (2002), Distinguished Achievement Award from the American Society of Preventive Oncology (2002), the Abraham Lilienfeld Award from the American College of Epidemiology (2005), HHS Secretary's Award for Distinguished Service (2004), NIH Distinguished Investigator (2019) and numerous other awards from NIH and PHS.



Hoover gives the 17th annual AACR-American Cancer Society Award Lecture in 2008.

Hoover is a member of the American Epidemiological Society and the Association of American Physicians. He has contributed to more than 600 peer-reviewed publications, 32 editorials or commentaries and 45 book chapters.

“Dr. Hoover has been a major figure in shaping the field of cancer epidemiology, inspiring many others by his insight and example, while training and mentoring some of the foremost cancer epidemiologists in this country and abroad, said DCEG director Dr. Stephen Chanock. “His creative approaches to interdisciplinary studies, which utilize clinical observations and laboratory methods, have been adopted by epidemiologists throughout the world.”

In retirement, Hoover will serve as scientist emeritus to the division. **R**



At a recent NINR Director's Lecture, Dr. Barbara Riegel described her research program in adult chronic illnesses such as heart failure.

Riegel Explores Intersection of Self-Management, Symptom Science

Dr. Barbara Riegel recently presented the NINR Director's Lecture, "At the Intersection of Self-Management and Symptom Science." Like many events originally scheduled to take place on campus,

Riegel's lecture was presented online in response to the Covid-19 pandemic.

Professor of gerontology at the University of Pennsylvania School of Nursing and codirector of the International Center for Self-Care Research, Riegel described her research program in adult chronic illnesses such as heart failure.

She began studying heart failure after finishing her Ph.D., when, as a clinical nurse researcher, she was tasked with determining which patients in a health care system were repeatedly admitted and what could be done to reduce these readmissions.

After discovering that it was heart failure patients who were repeatedly readmitted, Riegel began a series of heart failure disease management trials, marking the start of her research in this population.

"I never saw myself as a theorist when I went into this," Riegel admitted, describing how her research led to a series of theoretical developments. She considers her major area of impact in measurement, however, including the Self-Care of Heart Failure Index, as well as self-care inventories for hypertension, coronary heart disease, diabetes, COPD, chronic illness and others available at <http://self-care-measures.com>.

View Riegel's full lecture at <https://www.youtube.com/NINRnews>. **R**

AAPI Heritage Month Marked at NIH

In celebration of Asian American and Pacific Islander (AAPI) Heritage month, NIH's chapter of the Federal Asian Pacific American Council (FAPAC) held a virtual meeting on May 28 to discuss the Covid-19 pandemic and understand the issues the AAPI community is facing.

"The AAPI community is in a direct collision course of a Covid-19 tsunami, even as we continue to serve the country in combating the pandemic at multiple fronts," said NIBIB staff scientist Dr. Joy Zhao. "This virtual conversation was aimed to address the important questions about how to deal with increased discriminatory experiences in the AAPI communities, how to stay united in the pandemic and how to serve the community in need."

Featured speakers included Dr. Francisco Sy, chair of the department of environmental and occupational health, University of Nevada; Rita Pin Ahrens, executive director, OCA-Asian Pacific American Advocates; Dr. Maryland Pao, clinical director and deputy scientific director, NIMH; Dr. Clarence Lam, state senator, Maryland General Assembly; and Olivia Adrian, president, FAPAC.

More than 290 attendees joined the event celebrating AAPI culture and contributions during the pandemic.

POSTDOC AWARDED

NINDS Researcher Receives Pew Award for Latin Americans

The Pew Charitable Trusts has announced that Dr. Eunice Domínguez-Martín, an NIH postdoctoral fellow, is one of 10 recipients of an award from Pew's Latin American Fellows Program in Biomedical Sciences.

Every year, the program honors 10 of Latin America's brightest biomedical researchers for postdoctoral training in the U.S. This includes a \$30,000 per year annual salary stipend for 2 years and an additional \$70,000



Dr. Eunice Domínguez-Martín, an NIH postdoctoral fellow, is one of 10 recipients of an award from Pew's Latin American Fellows Program in Biomedical Sciences.

grant for equipment and supplies to recipients who return to Latin America as independent investigators.

Domínguez-Martín works in the laboratory of Dr. Richard Youle, senior investigator at the National Institute of Neurological Disorders and Stroke. She is currently conducting pre-clinical research on the role the innate immune system may play in damaging the brain during Parkinson's disease.

Originally from Mexico, Domínguez-Martín has a bachelor's degree in basic biomedical research and a master's degree in biochemistry from the National Autonomous University of Mexico (UNAM). In 2018, she earned a joint Ph.D. in biomedical research from UNAM and in molecular biosciences from the Autonomous University of Madrid in Spain. Before joining NIH, Domínguez-Martín primarily studied the chemical reactions behind a cell's response to stress, including the accumulation of misfolded proteins.