Report to the National Advisory Environmental Health Sciences Council

Director, NIEHS
June 2, 2020

Appropriations Overview

	FY 2018 Enacted	FY 2019 Enacted	FY 2020 President's Request	FY 2020 House Bill	FY 2020 Senate Bill	FY 2020 Enacted	Δ Between FY2020 and FY 2019 (%)
NIEHS	$751,143,000	$774,707,000	$666,857,000	$812,570,000	$815,729,000	$802,598,000	↑ 3.6%
NIH (LHHS)[a/]	$37,084,000,000	$39,079,000,000	$34,151,048,000	$41,084,000,000	$42,084,000,000	$41,684,000,000	↑ 6.7%
Common Fund[b/]	$600,716,000[c/]	$619,166,000	$532,967,000	$617,761,000	$638,751,000	$626,511,000	↑ 1.2%
Superfund	$77,349,000	$79,000,000	$66,581,000	$80,000,000	$81,000,000	$81,000,000	↑ 2.6%
NIEHS/ DOE Training[d/]	$10,000,000	$10,000,000			$10,000,000	$10,000,000	No Change

a/ Excludes Mandatory Type 1 Diabetes Research and Superfund.
b/ Includes addition of $12.6 million for the Gabriella Miller Kids First Act pediatric research initiative.
c/ Excludes $60 million "All of US" funding which the committee moved to the NIH Office of the Director.
d/ Appropriations Committee report language supporting the transfer of funds from the U.S. Department of Energy's Defense Environmental Cleanup account to NIEHS for the NIEHS/DOE Nuclear Worker Training Program.

Science Advances

One NIEHS (NIEHS authors' groups in parens)

DNA methylation in mice is influenced by genetics as well as sex and life experience. Grimm SA [DIR], T Shimbo [DIR], M Takaku [DIR], JW Thomas, S Auerbach [NTP], BD Bennett [DIR], JR Bucher [NTP], AB Burkholder [DIR], F Day [DIR], Y Du [DIR], CG Duncan [DIR], JE French [NTP], JF Foley [NTP], J Li [DIR], BA Merrick [NTP], RR Tice [NTP], T Wang [DIR], X Xu [DIR], PR Bushel [DIR], DC Fargo [DIR], JC Mullikin and PA Wade [DIR]. *Nat Commun* (2019) v. 10 (1) [ePub] http://dx.doi.org/10.1038/s41467-018-08067-z
(Th.1, Goal 1, 2; Th. 3, Goal 1,3,4)

DNTP

Effect of GenX on P-Glycoprotein, Breast Cancer resistance protein, and multidrug resistance-associated protein 2 at the blood-brain barrier. Cannon RE [NTP], AC Richards [NTP], AW Trexler [NTP], CT Juberg [NTP], B Sinha [NTP], GA Knudsen [NTP] and LS Birnbaum [NTP]. *Environmental Health Perspectives* (2020) v. 128 (3): e37002
https://doi.org/10.1289/ehp5884
(Th.1, Goal 1, 2; Th. 2, Goal 5)

DIR

Epithelial Membrane Protein 2 Governs Transepithelial Migration of Neutrophils Into the Airspace. Lin WC [DIR], KM Gowdy [DIR], JH Madenspacher [DIR], RL Zemans, K Yamamoto, M Lyons-Cohen [DIR], H Nakano [DIR], K Janardhan [NTP], CJ Williams [DIR], DN Cook [DIR], JP Mizgerd and MB Fessler [DIR]. *J Clin Invest (2020) 130(1):157–170.*
https://doi.org/10.1172/jci127144
(Th.1, Goal 1)

DERT

Using methylome data to inform exposome-health association studies: An application to the identification of environmental drivers of child body mass index. Cadiou S, Bustamante M, Agier L, Andrusaityte S, Basagaña X, Carracedo A, Chatzi L, Grazuleviciene R, Gonzalez JR, Gutzkow KB, Maitre L, Mason D, Millot F, Nieuwenhuijsen M, Papadopoulou E, Santorelli G, Saulnier PJ, Vives M, Wright J, Vrijheid M, Slama R. *Env Int (2020) May 138:105622.*
https://www.ncbi.nlm.nih.gov/pubmed/32179316
(Th.1, Goal 1, 2, 4; Th. 2, Goal 1)

NIEHS COVID-19 Updates

NIEHS-wide COVID-19 Activities

In order to best respond to the frequently changing conditions related to the current COVID-19 pandemic, NIEHS Senior leadership is participating in weekly focused meetings with NIH and NIEHS Emergency Teams. Beyond the NIEHS community, there is coordination with state and local "Stay at Home" orders. We are maximizing telework and only allowing for mission-essential work onsite. If personnel must come to campus, masks are required as well as temperature checks for all personnel entering NIEHS facilities. In addition, the NIH has released its NIH Framework for Returning to Physical Workspaces, summarized in the table below.

Table 1. Path to full return and the new normal

	Current State & Baseline for Planning	Group A Onsite Specific Work	Group B Increasing Onsite Specific Work	Group C Integration of Teleworkers	Group D Full Return
Indicators	Developing agency plan; increased need for patient care	Data supports moving forward	At least 3 weeks & data supports moving forward	At least 3 weeks & data supports moving forward	At least 3 weeks & data supports moving forward
Principles	Assess Environmental State and Prep IC Workforce Plans	Work that cannot be completed remotely	Work that is difficult to complete remotely	Integration of teleworkers	Full Return to Workspace
Staffing	Current State: IRP exceptions, employees supporting increasing CC patient census	Staff whose work must be done onsite (i.e. campus support, intramural research)	Staff whose work is best done onsite and Tier 3 staff on weather/safety leave	Staff who can successfully telework but are willing and able to return on site	All Staff
Health & Safety	Current State	Targets for staffing; Physical distancing (6ft); All meetings remote and mission critical travel	Targets for staffing; Physical distancing (6ft); All meetings remote and mission critical travel	TBD	TBD
Timeline	Present	Earliest – June	Earliest – July	TBD	TBD

DIR COVID-19 activities

DIR Scientist are actively contributing to the COVID-19 research enterprise. The following represent a growing list of new basic, clinical and population science research projects in DIR directed at increasing our understanding of the COVID-19 pandemic and development of clinical interventions. Please contact Hans Luecke for updates or additional details on these exempted research efforts.

Table 2. DIR COVID-19-related research activities

Lab/Branch	***Project Title***	***PI/Core Director***
BCBB	ToxPI GIS COVID19 Dashboard	Alison Motsinger-Reif
CRB	Epigenetic control of ACE2 in human cranial placode cells	Natalie Shaw
CRB	COVID-19 Global Rheumatology Alliance	Fred Miller/ Lisa Rider

CRB	COVID-19 Serological assay of essential employees at the NIEHS	Stavros Garantziotis
EB	The influence of COVID-19 on fertility planning, conception and pregnancy loss	Anne Marie Jukic
EB	COVID-19 in the Sister Study, Agricultural Health Study, and GuLF STUDY cohorts - the COPE Consortium	Dale P. Sandler
EB	A national survey to capture disparities in COVID-19 related events	Chandra L. Jackson
GISBL	Testing activity of the anti-viral insect protein AZ1 against COVID-19	Geoffrey Mueller
GISBL	Monitoring mutational signatures in the genomes SARS-CoV-2 isolates across the world	Dmitry Gordenin
GISBL	Design of Heparan Sulfate (HS) Therapeutics Against COVID-19 Viral Infection	Lars Pedersen
GISBL	Development of pipelines for structural studies on SARS-CoV-2 S protein	Mario J. Borgnia
GISBL	Modeling SARS-Cov-2 S protein in the water/air interface (support Cryo-EM efforts)	Lalith Perera
IIDL	Human air-liquid interface (ALI) cultures for testing anti-COVID19 reagents	Stavros Garantziotis
IIDL	Smoking, immune senescence and COVID-19 morbidity	Douglas Bell
IIDL	Role of SARS-CoV-2 spike protein O-glycosylation in lung inflammation	Darryl Zeldin
IIDL	Antiviral activity of human milk lactoferrin against enveloped coronavirus	Steven R. Kleeberger
IIDL	Purinergic Intervention for Covid-19 using Small Molecule Drugs	Donald Cook
IIDL	Investigation of role of EMP2 in COVID-19 infection	Michael Fessler
IIDL	Hyperplexed sample barcoded screening for SARS-CoV-2 by NGS	Douglas Bell
RDBL	Role of RNA modifications in coronaviruses replication	Marcos Morgan
RDBL	Role of COVID19 Interacting proteins in male and female reproduction.	Francesco DeMayo
RDBL	Humanized ACE2 Mouse Models of SARS-Cov-2 Infection	Artiom Gruzdev
STL	Structural Characterization of Covid-19 RNA Processing Factors	Robin Stanley
STL	Boosting innate immune responses to RNA viruses with inositol pyrophosphates.	Stephen Shears

GISBL	Designing Boronate Inhibitors of the 3CL Protease	Geoffrey Mueller
GISBL	Targeting the viral RNA polymerase to develop therapeutics for COVID-19	Samuel Wilson
STL	Boosting innate immune responses to RNA viruses with inositol pyrophosphates.	Stephen Shears

Meetings and Events

Past Events

PEPH 2020: Past Present and Future. Nearly 200 individuals involved with the NIEHS Partnerships for Environmental Public Health (PEPH) met Feb. 12-13 to celebrate the program's first 10 years and shape its vision for the next decade. **PEPH 2020: Past, Present, and Future** drew researchers, health advocates, science communicators, educators, policy experts, and public health officials to the Durham Convention Center in Durham, North Carolina. Workshops, panels, and poster presentations spurred ideas and debate, provided networking opportunities, and displayed the breadth of PEPH initiatives. Some participants discussed work to increase scientific literacy and help disadvantaged communities use low-cost technology to monitor pollution. Others described their efforts to reduce environmental health disparities. More than 50 posters were shared in the poster session. **Th. 2, Goals 2, 4, 6**

Music and Science. Can science can tell us why we create music and how the art form might improve our health? Those questions — and live jazz improvisation — entertained a packed crowd at **Music and Science**. The lunchtime event was hosted by NIEHS and the Research Triangle Foundation (RTF), Feb. 18. Headlining the event were bassist John Brown, director of Duke University's jazz program and professor of the practice of music, and Richard Mooney, Ph.D., professor of neurobiology at Duke. Mooney's lab studies the neurobiology of hearing and communication, with special emphasis on the neural mechanisms of vocal learning, production, and perception. After brief introductions by Linda Rozet, a senior director at RTF who helped coordinate the event, and NIEHS Acting Director Rick Woychik, Ph.D., the program began with a jazz set by Brown and guitar accompanist Kevin Van Sant. **Th. 2, Goal 2; Th. 3, Goal 3**

Uterine Fibroid Symposium. The basic science of uterine fibroids — benign tumors that grow in the uterus and cause an array of health problems — drew researchers from as far away as Spain to the **Uterine Fibroids Symposium** Feb. 28 at NIEHS. Topics ranged from molecular techniques for mapping uterine fibroid cells to the use of green tea extract as a potential treatment. Experts shared scientific advances and environmental connections at the meeting co-sponsored by the Campion Fund. The event featured two distinguished lectures, 12 talks, and oral presentations and posters by early-career investigators. Organizers also provided time for networking and forging new collaborations. **Th. 1, Goal 1; Th. 2, Goal 2**

2020 Worker Training Program Virtual Workshop. Strategies to prevent spread of COVID-19 and protect frontline workers were front and center during the **2020 Worker Training Program (WTP) virtual workshop** March 17. Federal agency representatives, infectious disease experts,

and health and safety professionals shared timely information. WTP has a long history of training and preparing workers who face potential exposure to hazardous pathogens, such as swine flu and Ebola. WTP's national network of trainers and experts will prove critical in protecting first responders and other front-line workers during the COVID-19 pandemic. Workshop speakers discussed transmission of SARS-CoV-2, which is the virus that causes COVID-19, as well as worker protections, and federal, state, and local training efforts. **Th. 2, Goals 2, 5; Th. 3, Goals 3, 4**

Postcards from Durham. NIEHS and the Durham, North Carolina, community were treated to an online tour of their common past in April. John Schelp, special assistant for community engagement and outreach in the institute's Office of Science Education and Diversity (OSED), narrated "**Postcards from Durham**," a three-part history series. The third event, held on Facebook April 16, covered the beginnings of Research Triangle Park (RTP) and the effects of NIEHS coming to the Tar Heel State. Schelp used postcards from his private collection to enhance the learning experience. Preservation Durham and the Museum of Durham History sponsored his presentations. Two earlier sessions highlighted downtown, West Durham, Duke University, Hayti, and other areas. **Th. 2, Goal 2**

Climate, health, and the environment lecture. The NIEHS Global Environmental Health Program has commenced a new lecture series on Climate, Environment, and Health. The first lecture was given by webinar on May 6th at 11 AM. NIEHS Senior Advisor for Public Health John Balbus, M.D., M.P.H. opened the series with a lecture entitled "How Climate Changes Health and Why You Should Care". The seminar will offer compelling scientific talks on climate science, how changes in the global climate affect health through a variety of environmental pathways, and promising research approaches to better understand how the changes we see in climate impact health now and in the future. We will also learn how climate actions taken now can protect us from future harm. The second seminar will be given by Jason West, Ph.D., Professor Department of Environmental Sciences and Engineering, UNC Gillings School of Global Public Health. He will present a lecture entitled "Understanding Global Climate Change and How It Affects Air Quality and Human Health." The talk will provide a deeper dive into climate science and approaches to studying the interactions between climate change and air quality. **Th. 2, Goals 2, 5**

Upcoming Events

- **ESEHD Integrating the Science of Aging and Environmental Health Research,** Webcast, June 9-10
- **NIEHS Global Environmental Health Day 2020,** NIEHS, July 1
- **Shining a Light on Base Excision DNA Repair,** NIEHS, August 6-7
- **ESEHD Workshop on Predicting Human Health Effects from Environmental Exposures: Applying Translatable and Accessible Biomarkers of Effect,** TBD, August 12-13
- **Estrogen Receptor Hormone Action Symposium,** NIEHS, September 18, 2020
- **APHA 202 Annual Meeting and Expo,** San Francisco, October 24-28

NIEHS News and Highlights

Staff Updates

- **Shawndall Fox** joined NIEHS as Deputy Chief of Administrative Services in the Administrative and Research Services Branch (ARSB).
- **Kyle Messier, Ph.D.,** is the newest National Institutes of Health (NIH) Earl Stadtman Tenure-Track researcher to join NIEHS. He is the first Stadtman researcher to join the NIEHS Division of the National Toxicology Program (DNTP). Messier's research — unique at NIEHS — uses a type of statistical model known as spatiotemporal. These models look for patterns in data and predict variables, such as exposures or disease, at new locations or during certain time frames.

Facilities Updates

- **Rodbell Auditorium—**After many months of hard work, construction is complete, and the Rodbell Auditorium is open for use! An open house for viewing was held on March 10.

Awards and Recognition

NIEHS

- **HHS Green Champion Award Winners**
  - Category: Energy and Fleet Management
    Team: ***Tim Schilens, Terry Wells, Heather Davis-(ORF/FMB)***
    Project: All-Electric Vehicles -- Reduced the site's carbon footprint by more than 30,000 pounds of carbon emissions, and fuel costs by $25,000 over a five-year period by using three all electric low speed vehicles for the Maintenance and Operations program.
  - Category: Energy and Fleet Management
    Team (from NIEHS): ***Jason Williams, Leesa Deterding-(DIR/ESCBL)***
    Project: NIH Freezer Challenge -- The NIH held its first freezer challenge to reduce energy consumption from laboratory grade freezers within NIH laboratories. Laboratories were challenged to adopt one or more initiatives from a set of freezer management techniques. Their efforts in this challenge will save the NIH 14,975 kilowatt hours, $12,647, and 48 metric tons of carbon dioxide-equivalent greenhouse gas emissions annually.
  - Category: Environmental Stewardship
    Team: ***Neil Grove, Debbie Gaffney, Gordan Caviness, Kethard Thomas-(DIR/CMB); Paul Johnson, Bill Steinmetz-(OM/HSB), Paul Poliachik, Tim Schilens, Bill Stutzbach, Dennis Will-(ORF/FMB)***
    Project: Vivarium Animal Feed Composting Initiative -- Successfully diverted approximately 46 tons per year of used, unconsumed animal feed to composting.
  - Category: Sustainable Design and Facilities
    Team: ***Alison Karver-(ORF/FMB); Debra Del Corral-(OM/OSB), Amanda Thompson-(OM/OSB); Rhonda Carroll-(OM/ASAB)***

Project: Rall Building Public Space Renovations -- Enlarged space encourages multi-lateral use, as well as on-site conferences instead of renting and traveling to offsite venues. Projects to replace skylights and the Main Entrance store front with electrochromic glass resulted in savings of over 40,000 KWH of energy and represent a coordinated sustainable design and renovation effort.

- Category: Water Use Efficiency and Management
  Team: ***James (Victor) Stancil, P.E.; Kyle Askins, P.E.; Brian Harris-(ORF/FMB); Daniel Burk-(ORF/OA)***
  Project: Rall Building Chilled Water Fan Coil Loop Piping Replacement -- Reduced pump energy as a result of clearing flow restrictions in the piping and eliminated the risk for catastrophic failure of corroded 40-year old steel pipes. Estimated annual water savings is 119,000 gallons, equivalent to 4,760 ten-minute showers or 901,300 bottles of drinking water.

- ***Sing-Wai Wong, D.D.S., Ph.D.,*** a postdoctoral fellow in the Inflammation and Autoimmunity Group, Immunity, Inflammation and Disease Laboratory was awarded the **2020 IADR/Philips Oral Healthcare Young Investigator Research Grant.** The grant provides funding for a postdoctoral fellow that is within 12 months of completing a Ph.D. and wishes to establish an independent program of research. The grant is awarded on a competitive basis annually. The award is sponsored by Philips Oral Healthcare and offered through the International Association for Dental Research (IADR) Periodontal Research Group.
- **Big Picture, Small Talk Communications Challenge Winners -** Each receive a $1,500 travel stipend from the Office of Fellows' Career Development:
  - **Bevin Blake**, Predoctoral Fellow in the National Toxicology Program Laboratory
  - **Jacob Kresovich**, Postdoctoral Fellow in the Epidemiology Branch
  - **Niketa Bhawsinghka**, a Visiting Postdoctoral Fellow in the Genome Integrity and Structural Biology Laboratory
- **Jeff Church**, Chief of the Health and Safety Branch (HSB), was selected for a **Fellow Award from the American Industrial Hygiene Association (AIHA)**. Only 5% of AIHA members can qualify for this prestigious award. A Mark of Excellence ceremony is scheduled for June 3.
- **SOT Awards**
  - The Regulatory and Safety Evaluation Specialty Section chose **Katelyn Lavrich, Ph.D.,** from NTP for the **Postdoc Excellence Award**. Lavrich uses 3D spheroid cultures of human liver cells called primary hepatocytes (PHH) to develop better toxicity tests.
  - The SOT Food Safety Specialty Section selected **Mimi Huang, Ph.D.,** for the **Frank C. Liu Early Career Scientist Award**. Huang studies per- and polyfluoroalkyl substances (PFAS) to determine connections between chemical structures and toxicities. Huang, who is an Intramural Research Training Award (IRTA) fellow in the Toxicology Branch of the NIEHS Division of the National Toxicology Program (NTP), is especially interested in understanding effects of dietary exposure to PFAS.

Grantees/Others

- **Dr. José Cordero** was awarded the **University Georgia's College of Public Health's Excellence in Research Award**. Dr. Cordero is the Patel Distinguished Professor of Public Health and Head of our Department of Epidemiology and Biostatistics. Originally trained as a pediatrician, Cordero has dedicated his career to addressing maternal and child health as well as minority health and health disparities. He currently co-directs the

Puerto Rico Test site for Exploring Contamination Threats (PROTECT) Center as well as the Center for Research on Early Childhood Exposure and Development (CRECE), both of which examine how exposure to environmental contaminants contributes to the high rate of preterm birth in Puerto Rico.

- Renowned environmental health scientist **Frederica Perera, Ph.D.,** delivered the **2020 NIEHS Spirit Lecture** on Mar. 5. Her talk was titled "Translational Research to Prevent Environmental Threats to Children: From Chemicals to Climate Change." Perera is a Columbia University professor and the founding director of the school's Center for Children's Environmental Health, which is co-funded by NIEHS. Her work focuses on pregnant women, children, and minority groups, who can be especially vulnerable to pollution.
- **SOT Awards**
    - **James Luyendyk, Ph.D.,** from Michigan State University (MSU) is the 2020 winner of the **SOT Achievement Award**. With NIEHS funding, Luyendyk is studying mechanisms of liver fibrosis, which is one way that substances may cause liver damage.
    - The **Toxicological Sciences Paper of the Year** was co-authored by NIEHS council member **Robyn Tanguay, Ph.D.,** from Oregon State University (OSU). She directs the Superfund Research Program center at OSU.

Legislative Update

Congressional Hearings and Briefings

House Science Committee FY2021 Federal R&D Budget Overview Hearing, Feb. 27, 2020
On February 27, 2020, the House Committee on Science, Space and Technology held a full committee hearing entitled, "*A Review of the Administration's Federal Research and Development Budget Proposal for Fiscal Year 2021*." The sole witness was Kevin K. Droegemeier, Ph.D., Director, White House Office of Science and Technology Policy (OSTP). During the hearing and in response to questions from Representative Lizzie Fletcher of Texas, the OSTP Director explained the U.S. Environmental Protection Agency (EPA) is currently focusing its R&D energies on six integrated programs: air and energy, chemical safety, homeland security, human health risk assessment, safe and sustainable water resources, and sustainable and healthy communities. The Director further explained the three top-line priorities within that framework are PFAS research, lead research, and harmful algal blooms research—all of which he noted align with Executive Branch interagency coordination on contaminants of emerging concern (CECs). Other topics addressed during the hearing relate to STEM education and to research activities of the U.S. Global Change Research Program (USGCRP), the U.S. Department of Energy (DOE), the National Oceanic and Atmospheric Administration (NOAA), and the National Aeronautics and Space Administration (NASA).

House and Senate Appropriations Subcmte. NIEHS Superfund Briefing, Feb. 28, 2020
On February 28, 2020, Richard P. Woychik, Ph.D., NIEHS Acting Director, briefed staff of the House and Senate Appropriations Subcommittees on Interior, Environment, and Related Agencies about the NIEHS Superfund Research Program (SRP) and the NIEHS Worker Training Program (WTP)—the two components of the National Institutes of Health (NIH) budget that fall within the jurisdiction of this particular Appropriations Subcommittee. Other similarly situated components

of the HHS budget that fall within this Subcommittee's jurisdiction are the Indian Health Service (IHS) and the Agency for Toxic Substances and Disease Registry (ATSDR). Of note, the Food and Drug Administration (FDA) falls under the jurisdiction of the Appropriations Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies. All other operating and staff divisions of HHS, including all other parts of the NIH budget, fall within the jurisdiction of the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies. At the February 28th briefing, Subcommittee staff asked Dr. Woychik about the typical size of SRP research grants, the distribution of research on per- and polyfluoroalkyl substances (PFAS) across the SRP, the process utilized by NIEHS in developing Funding Opportunity Announcements (FOAs), and how NIEHS is expending the $2 million increase Congress provided for the SRP in FY2020 as compared with the FY2019 enacted level. The Subcommittee staff received the NIEHS Acting Director for this briefing in lieu of a formal hearing and as a result of facilitation by the Office of the HHS Assistant Secretary for Financial Resources (ASFR).

House Appropriations Subcmte. Hearing on FY2021 NIH Budget Request, Mar. 4, 2020

On March 4, 2020, the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies held its annual budget hearing for NIH. Francis S. Collins, M.D., Ph.D., NIH Director, testified at this hearing and was accompanied at the witness table by five NIH Institute Directors: Diana Bianchi, M.D., Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD); Anthony S. Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases (NIAID); Gary H. Gibbons, M.D., Director of the National Heart, Lung, and Blood Institute (NHLBI); Ned Sharpless, M.D., Director of the National Cancer Institute (NCI); and Nora D. Volkow, M.D., Director of the National Institute on Drug Abuse (NIDA).

In her opening remarks, Representative Rosa L. DeLauro of Connecticut, the Subcommittee Chairwoman, noted Congress on a bipartisan, bicameral basis has increased NIH funding by $11.6 billion or 39% over the past five years. She noted that last year alone—for FY2020 NIH appropriations—Congress provided a $2.6 billion increase over the FY2019 enacted level. She further stated the Subcommittee intends to move forward on a bipartisan basis to continue increasing investments in NIH research and "to build on the progress made in recent years." In particular, Chairwoman DeLauro singled out her support for the $25 million that was appropriated in FY2020 for firearm violence prevention research, $12.5 million of which was appropriated to NIH, and for maintaining—as the budget requests—funding for research on flu, including for development of universal flu vaccine. She expressed concern with a proposed $559 million reduction for NCI "at a time of unprecedented promise in cancer research" and growing demand for NCI grants. She noted that with few exceptions the reductions proposed in the budget request would affect every NIH Institute and Center, and that last year Congress, in addition to providing new funding for several initiatives, was able to provide a 3.3% increase for each NIH Institute and Center. She expressed her desire that the Subcommittee "keep up that momentum" before remarking, "biomedical research is one of the most important investments a country can make because it gives the gift of life."

Representative Tom Cole of Oklahoma, the Subcommittee's Ranking Minority Member, opened his remarks by stating the NIH panel of witnesses are "extraordinary custodians" of the investment in NIH the Subcommittee has made on a bipartisan basis for multiple years. He further stated he too intends to work for continued increases for the NIH budget and that Congress in recent years has

gone "above and beyond" what Presidents have asked for in terms of NIH funding. He remarked the NIH increases are the result of initiative from Congress because its Members are "close to the people" and have a "keen sense and awareness of how Americans value the endeavors at NIH." He further stated that a "sustained, steady commitment to increase NIH funding is critical to ensuring our Nation's future as a leader in biomedical research and unlocking cures to so many diseases burdening our strained health care system. The hard work and innovation this funding fosters is part of the sustaining force of the United States' economic growth. To reduce NIH funding at this juncture would erode the progress that has been made over the past five years, signal to the research community instability, and possibly delay advances in modern medicine, … including unlocking the power of precision medicine."

Representative Cole also spoke of progress with cancer research and Alzheimer's research, and cautioned against the proposed changes in the budget request to the negotiation for indirect costs or funds included as part of NIH grants to cover facilities and administration. He remarked that such funds "serve as a foundational element for research" and called for the continuation of the general provision contained in the FY2020 appropriations law that precludes any changes to indirect costs policy.

Representative Nita Lowey of New York, the Chairwoman of the full House Appropriations Committee, stated she believes the Committee's commitment to NIH will remain as strong as ever. She spoke of the importance of research on heart disease, cancer, Alzheimer's disease and related dementias, the vaping epidemic, and the coronavirus. Representative Lowey also extolled the progress with NIH research she has witnessed over the years since she joined the Labor, HHS, Education and Related Agencies Appropriations Subcommittee in 1993, including as it relates to breast cancer, the Human Genome Project, childhood development, the human brain, precision medicine, and advancement of women in the laboratory sciences. She noted this hearing likely marks her last NIH budget hearing given she is not seeking re-election to the next Congress. In closing, Representative Lowey stated, "never in human history has medicine had more to offer."

In his opening remarks, Dr. Collins provided an overview of NIH's critical role in enhancing the Nation's health through scientific discovery. He remarked that "scientific and technological breakthroughs generated by NIH-supported research are behind much of the gains our country has enjoyed in health and longevity." He further noted the budget will support NIH's ability to fund the highest priority scientific discoveries while also maintaining fiscal stewardship of Federal resources, and that the budget prioritizes biomedical research to confront the Nation's greatest medical challenges and opportunities, including precision medicine, the opioid crisis, and HIV/AIDS.

Dr. Collins indicated NIH's backlog of maintenance and repair (BMAR) is approximately $2.1 billion. He referenced the independent review of the facility needs of NIH's main campus by the National Academies of Sciences, Engineering, and Medicine (NASEM) that was released in August 2019 and that substantiates the need for an increase in NIH facilities funding and additional flexibilities to reduce BMAR as requested in the FY2021 budget request. The budget request proposes $300 million to support multiple biomedical research infrastructure priorities at NIH-owned sites and to limit the deterioration of its facilities. The budget request also proposes a general provision to allow NIH to address facility needs through a new transfer authority.

Additionally, Dr. Collins highlighted budget priorities to advance research and care for premature babies, the Helping to End Addiction Long-term (HEAL) Initiative relative to opioids and pain research, the Childhood Cancer Data Initiative, the NIH-funded Centers for AIDS Research, the NIH-wide HIV research program, universal flu vaccine research, tick-borne disease (including Lyme disease) research, Artificial Intelligence (AI) and Machine Learning, and gene therapy and gene editing research.

Dr. Collins and the five Institute Directors that accompanied him at the witness table for this hearing fielded a number of questions from multiple Subcommittee members on a broad array of topics. Of particular relevance to NIEHS, Chairwoman DeLauro asked Dr. Collins to provide an overview of the NIEHS Worker Training Program (WTP) and address whether the Program could help the Nation respond to the COVID-19 pandemic. In response, Dr. Collins testified to the capabilities of the WTP and how they align with protecting workers at risk to infectious disease transmission. Two days after the hearing, on March 6, 2020, Congress enacted into law, the *Coronavirus Preparedness and Response Supplemental Appropriations Act*, U.S. Public Law 116-123, which is considered phase one of an ongoing phased response to the pandemic from Congress. This phase one law appropriated $10 million, to remain available until September 30, 2024, to the NIEHS WTP for "worker-based training to prevent and reduce exposure of hospital employees, emergency first responses, and other workers who are at risk of exposure to coronavirus through their work duties." On April 3, 2020, HHS transmitted to the Congressional Appropriations Committees the spend plan required by Section 305 of the Act for this $10 million.

As of this writing, a FY2021 NIH budget hearing before the corresponding Senate Subcommittee remains unscheduled. Chairwoman DeLauro announced at the March 4th House hearing that the House Subcommittee may hold a second hearing about NIH later this year to accommodate participation from additional NIH Institute and Center Directors than the five Institute Directors that were invited to appear on March 4th. Last year two NIH hearings were held by the Subcommittee, the first being the annual budget hearing on April 2, 2019, involving the Directors of NIAID, NHLBI, NCI and NIDA in addition to Dr. Collins, and the second being an additional hearing held on September 25, 2019, involving the Directors of the National Center for Advancing Translational Sciences (NCATS), the National Library of Medicine (NLM), the National Center for Complementary and Integrative Health (NCCIH), the National Institute on Minority Health and Health Disparities (NIMHD), and the National Institute of Biomedical Imaging and Bioengineering (NIBIB). A possible second NIH hearing this year remains unscheduled as of this writing.

<u>Senate HELP Committee Hearing on COVID-19 Testing Technology, May 7, 2020</u>
On May 7, 2020, the Senate Committee on Health, Education, Labor, and Pensions (HELP) held a full committee hearing entitled, "*Shark Tank: New Tests for COVID-19*." Dr. Collins, NIH Director, joined Gary Disbrow, Ph.D., Acting Director of the Biomedical Advanced Research and Development Authority (BARDA), as a witness at this hearing. Dr. Collins fielded questions from the Committee about plans to spend the $1.806 billion Congress appropriated to NIH through the Phase 3.5 COVID-19 response and recovery package—entitled the *Paycheck Protection Program and Health Care Enhancement Act* (P.L. 116-139)—"to develop, validate, improve, and implement testing and associated technologies; to accelerate research, development, and implementation of point of care and other rapid testing; and for partnerships with governmental and non-governmental entities to

research, develop, and implement [these] activities." Specifically, Dr. Collins described the Rapid Acceleration of Diagnostics (RADx) initiative NIH launched on April 29, 2020, the aim of which is to speed delivery of accurate, easy-to-use, scalable tests to all Americans. Dr. Collins also fielded questions from Senators Bill Cassidy of Louisiana, Lisa Murkowski of Alaska, Tim Scott of South Carolina, and Doug Jones of Alabama, about the RADx-UP component of the RADx initiative for underrepresented populations. Dr. Collins explained RADx-UP ("Rapid Acceleration of Diagnostics Initiative-Underrepresented Populations Project") represents a major focus on implementation of strategies to enable testing of rural underserved and under-resourced populations among the hardest hit by the coronavirus and often those for which testing is less available. He explained RADx-UP will include the development of a centrist program that will allow demonstration projects to be put in place across the country in such communities. He further explained RADx will also include a program focused on the ethical, legal and social issues associated with COVID-19 diagnostic testing and ways to try to avoid the inequities associated with unequal access. Senator Lamar Alexander of Tennessee convened this hearing as the Senate HELP Committee Chairman and is focused on engaging NIH expertise to help the Nation find new technologies needed to rapidly produce tens of millions of COVID-19 tests. Senator Patty Murray of Washington State serves as the Committee's Ranking Minority Member and spoke at the hearing of the need to improve testing capacity and prepare appropriately "to have a safe, effective vaccine as soon as possible."

Senate HELP Committee Hearing on COVID-19 Response, May 12, 2020

On May 12, 2020, the Senate HELP Committee held a full committee hearing entitled, "*COVID-19: Safely Getting Back to Work and Back to School*." The four witnesses testifying at this hearing were: Dr. Fauci, NIAID Director; ADM Brett Giroir, M.D., USPHS, Assistant Secretary for Health, U.S. Department of Health and Human Services (HHS); Robert Redfield, M.D., Director of the Centers for Disease Control and Prevention (CDC); and Stephen Hahn, M.D., Commissioner, Food and Drug Administration (FDA). All four witnesses responded to a range of questions from Committee members about the coronavirus and pandemic response efforts.

Senate EPA Committee Hearing on EPA Oversight

On May 20, 2020, the Senate Committee on Environment and Public Works (EPA) held a full committee hearing entitled, "*Oversight of the Environmental Protection Agency*." Andrew Wheeler, J.D., EPA Administrator, was the sole witness. During the hearing, Committee members probed the work of the EPA relative to providing the public with updated information on which disinfectants and cleaning products can be safely used to prevent or minimize transmission of the coronavirus. The hearing also touched on EPA grant funding being made available to the States, territories and Tribes to help communities address the coronavirus, and EPA efforts to provide personal protective equipment to aid emergency and health professionals during the pandemic. Senator John Barrasso of Wyoming serves as the Committee's Chairman, and Senator Thomas R. Carper of Delaware serves as the Committee's Ranking Minority Member.

Legislation

To date, Congress has enacted four legislative packages to respond to the COVID-19 pandemic in a phased approach. The following summarizes these four laws as they relate to NIH, scientific research, and environmental health broadly. In sum, in three of the four laws enacted to date Congress has made emergency supplemental appropriations to NIH totaling $3.587 billion for

various COVID-19-related research and response activities—including for vaccine and treatment research, diagnostics and testing research, and worker-based training to prevent and reduce exposure of hospital employees, emergency first responders, and other workers who are at risk of exposure to coronavirus through their work duties. Seven of NIH's 27 Institutes and Centers receive direct supplemental appropriations in one or more of these three laws in addition to the NIH Office of the Director (OD) and the NIH Common Fund administered by OD. These seven Institutes and Centers are: NIAID, NIBIB, NCI, NHLBI, NCATS, NLM and NIEHS. Additionally, as of this writing, the House of Representatives has passed a fifth legislative package that proposes to make an additional $4.721 billion in supplemental appropriations to NIH. This House-passed package is subject to reconciliation with the Senate before it, or any alternative to the additional amount of funding proposed for NIH in the House-passed bill, would become law.

Phase 1: H.R. 6074, *Coronavirus Preparedness and Response Supplemental Appropriations Act*, U.S. Public Law 116-123, Enacted on March 6, 2020. Total: $8.3 billion.

- Includes $836 million for NIH available through FY2024 to prevent, prepare for, and respond to coronavirus divided as follows:
    - $826 million for NIAID; and
    - $10 million for NIEHS Worker Training Program (see related information above under the "House Appropriations Subcmte. Hearing on FY2021 NIH Budget Request, Mar. 4, 2020" heading for details about this appropriation).

Phase 2: H.R. 6201, *Families First Coronavirus Response Act*,
U.S. Public Law 116-127, Enacted on March 18, 2020. Total: $100 billion.

- No funds were appropriated to NIH under this law.

Phase 3: H.R. 748, *Coronavirus Aid, Relief, and Economic Security (CARES) Act,*
U.S. Public Law 116-136, Enacted on March 27, 2020. Total: $2 trillion.

- Includes $945.4 million for NIH available through FY2024 to prevent, prepare for, and respond to coronavirus divided as follows:
    - $706 million for NIAID;
    - $103.4 million for NHLBI;
    - $60 million for NIBIB;
    - $36 million for NCATS;
    - $30 million for Office of the Director (OD) Common Fund; and
    - $10 million for NLM.

- $75 million for the National Science Foundation (NSF) Research and Related Activities Account available through FY2021 to prevent, prepare for, and respond to coronavirus including to fund research grants and other necessary expenses.
- $60 million for the National Aeronautics and Space Administration (NASA) Safety, Security and Mission Services Account to remain available through FY2021 to prevent, prepare for, and respond to coronavirus.
- $6 million for the National Institute of Standards and Technology (NIST) Scientific and Technical Research and Services Account to remain available through FY2021 to prevent, prepare for, and respond to coronavirus by supporting continuity of operations, including measurement science to support viral testing and biomanufacturing.

- $2.25 million for EPA Science and Technology Account available through FY2021 to prevent, prepare for, and respond to coronavirus, $1.5 million of which is "for research on methods to reduce the risks from environmental transmission of coronavirus via contaminated surfaces or materials."
- Section 3832 extends the Special Diabetes Program for Type I Diabetes administered by NIH through November 30, 2020. The Program was previously scheduled to expire on May 22, 2020.

Phase 3.5: H.R. 266, *Paycheck Protection Program and Health Care Enhancement Act*, U.S. Public Law 116-139, Enacted on April 24, 2020. Total: $484 billion.

- Includes $1.806 billion for NIH to remain available until expended divided as follows:
  - $1 billion for OD to support a whole-of-NIH approach to testing research and development (see related information above under the "Senate HELP Committee Hearing on COVID-19 Testing Technology, May 7, 2020" heading about the NIH Rapid Acceleration of Diagnostics (RADx) initiative launched as a result of this appropriation);
  - $500 million for NIBIB for point of care and other rapid testing research and development; and
  - $306 million for NCI for serological testing development.

In addition to the four legislative packages that have become law to date and as mentioned above, the House of Representatives passed a fifth legislative COVID-19 response package on May 15, 2020, which is summarized below. It is unlikely to be enacted into law in the form it has passed the House. Any additional response package that would become law is predicated upon agreement being reached between the House and the Senate on identical legislation.

Phase 4 House-passed bill: H.R. 6800, *Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act*, Passed by the House of Representatives by a vote of 208-199 on May 15, 2020.

- Proposes $4.721 billion for NIH, available through FY2024, to prevent, prepare for, and respond to coronavirus divided as follows:
  - $4.021 billion for OD with transfer authority to the Institutes and Centers,
    - $3 billion of which is for "offsetting the costs related to reductions in lab productivity resulting from the coronavirus pandemic or public health measures related to the coronavirus pandemic;" and
    - $1.021 billion of which is "to support additional scientific research or the programs and platforms that support research."
  - $500 million for NIAID; and
  - $200 million for the National Institute of Mental Health (NIMH).

The section-by-section bill summary released by the House Appropriations Committee upon House passage of this bill describes the purpose of the proposed NIH funding as follows: "to expand COVID-19-related research on the NIH campus and at academic institutions across the country and to support the shutdown and startup costs of biomedical research laboratories nationwide."

- Section 10612 extends availability of FY2020 appropriated funds to NIH into FY2021.
- Section 10613 extends the period of disbursement for FY2015 appropriated funds to NIH that were obligated for multi-year research grants through FY2021.

Congressional Interaction

The Children's Inn at NIH Annual Congressional Reception, Feb. 11, 2020

On February 11, 2020, the annual Congressional networking reception held for The Children's Inn at NIH occurred on the House side of Capitol Hill, Washington, D.C. Aubrey K. Miller, M.D., NIEHS Senior Medical Advisor, and April Bennett, Program Manager in the NIEHS Office of the Director, Bethesda, Maryland, represented NIEHS at this widely attended event which is held in celebration of The Inn and to recognize the importance of bipartisan Congressional support for NIH research and children's health.

U.S. Government Accountability Office (GAO) Report and Recommendation

ICCVAM Metrics Workgroup and ICCVAM Biennial Progress Reports

On September 24, 2019, the U.S. Government Accountability Office (GAO), the non-partisan, independent auditing and investigative arm of Congress, publicly released its report entitled, "*Animal Use in Research: Federal Agencies Should Assess and Report on Their Efforts to Develop and Promote Alternatives*." In this report, which was requested by multiple members of Congress, the GAO recommends the NIEHS Director: (1) facilitate the establishment or designation of a workgroup of representatives of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) member agencies to develop metrics that the agencies could use to assess the progress they have individually or collectively made toward reducing, refining, or replacing animal use in safety testing for chemicals and medical products, and (2) incorporate those metrics into the Committee's biennial progress reports that NIEHS prepares and publishes on behalf the Committee. For background, in December 2000, through enactment of the *ICCVAM Authorization Act of 2000* (P.L. 106-545), Congress established ICCVAM as a "permanent interagency coordinating committee" of NIEHS under its National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)—an NTP Division office focused on the development and evaluation of alternatives to animal use for chemical safety testing. Currently, ICCVAM, with NIEHS leadership and administrative support, coordinates the efforts in this space of 16 different Federal agencies. On March 31, 2020, the HHS Office of the Assistant Secretary for Legislation (ASL) transmitted to the GAO a formal update prepared by NIEHS on the implementation of this recommendation. That written update informed the GAO that ICCVAM member agencies in November 2019 agreed to form a workgroup comprised of individuals within their respective agencies who are best suited to developing agency-specific metrics. The ICCVAM Metrics Workgroup held its first meeting in February 2020 and is, as of this writing, in the process of developing a document outlining its scope and charge along with proposed timelines and deliverables. The workgroup is meeting virtually on a semimonthly basis and its work is consistent with the ICCVAM Strategic Roadmap released in January 2018. ICCVAM's next biennial progress report is anticipated to be published by the end of July 2020 and is expected to incorporate metrics. The GAO considers the recent formation of the workgroup as implementing the first part of its recommendation and indicates it will continue to monitor the steps taken by NIEHS and ICCVAM to implement the second part of its recommendation.

Spotlight on NIEHS: Environmental Health in Precision Medicine

A person's health over the course of their lifetime is the result of a combination of their genes and their environment. The Human Genome Project revolutionized our ability to study the genetic contributions to human health and disease. NIH has now launched an equally ambitious and exciting effort to further our understanding of the causes of human diseases: the *All of Us* Program. This initiative aims to enroll a million or more diverse people living in the United States and collect data on their environment, genetics, family history, and lifestyle. These data will inform thousands of studies on a variety of health conditions, from cancer to diabetes to Alzheimer's. As part of the Precision Medicine efforts of *All of Us* and the International Common Disease Alliance (ICDA), NIEHS is working to identify the environmental factors in the equation—a person's so-called "exposome"—which is the sum of their chemical, dietary, psychosocial, and other exposures through air, water, food, and elsewhere (Figure 1). NIEHS is collaborating with geneticists and genome scientists across the nation and around the world to develop and apply the best new technologies to determine how such exposures interact with a person's genes both directly and indirectly, or "epigenetically," by modifying how genes are expressed. This convergence of scientific disciplines offers nearly unlimited potential to expand our capacity to solve the mysteries of human illness, enabling us to predict, prevent, and intervene in disease to promote healthier lives. NIEHS is working to develop infrastructure that will enable the inclusion of the exposome into the All of Us, ICDA, and other human clinical and population studies designed to enable Precision Medicine.

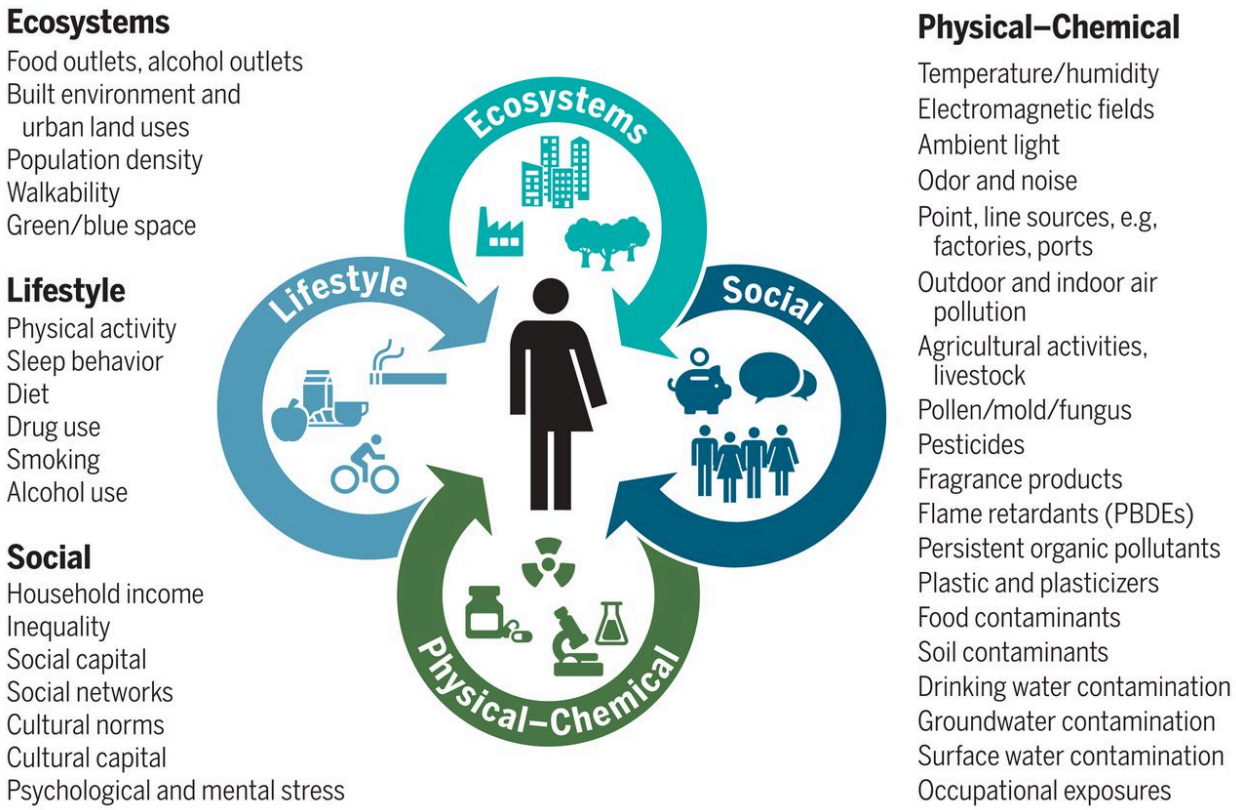

Figure 1. The exposome concept. From Roel Vermeulen et al. Science 2020;367:392-396

The ICDA aims to improve prevention, diagnosis, and treatment of common diseases by accelerating discovery from genetic maps to biological mechanisms to physiology and medicine, to benefit people around the world. NIEHS has been closely involved in the ICDA effort since its inception in September 2019 and has formed an internal working group (WG) to help guide the response and provide relevant environmental expertise as the ICDA drafts its white paper and recommendations.

NIEHS ICDA Working Group includes members from throughout the institute:

- Balbus, John (Senior Advisor for Public Health, OD)
- Balshaw, David (Chief, Exposure, Response, and Technology Branch, DERT)
- Bennett, L. Michelle (Director, Center for Research Strategy, NCI)
- Bowen, Tiffany (Scientific Program Analyst, Office of Policy, Planning, & Evaluation, OD)
- Chandler, Kelly (Health Science Policy Analyst, Office of Policy, Planning, & Evaluation, OD)
- Collman, Gwen (Acting Deputy Director, ODD)
- Cui, Yuxia (Health Scientist Admin., Exposure, Response, and Technology Branch, DERT)
- Fargo, David (Director of Environmental Science Cyberinfrastructure, OD)
- Hall, Janet (Clinical Director, DIR)
- Harrill, Alison (Geneticist, Biomolecular Screening Branch, DNTP)
- Kwok, Richard (Acting Health Science Admin., Population Health Branch, DERT)

Future Directions

The NIEHS WG has continued to meet monthly in order to coordinate revisions to the ICDA white paper and recommendations and to chart a course forward for continued NIEHS involvement. One of the planned activities include hosting a workshop entitled: "Integrating Multiscale Environmental Exposure Data in Large Population-Based Studies." The goals of this workshop are to:

- Demonstrate the latest development in the generation and integration of multiscale exposure data (across time, space and exposure types) and how that can be applied in large population-based studies for improved exposure assessment;
- Identify challenges and opportunities in multiscale exposure data integration and promote the incorporation of exposome in health studies for better understanding the role of the environment.

NIEHS plans to host this workshop in Spring 2021 and involve experts in environmental sensing technologies, Geographic Information Science (GIS), spatiotemporal modeling, epidemiology, biostatistics, and stakeholders from the genomics community. Expected outcomes of the workshop include: raising awareness of a variety of exposure data streams arising from different resources and technologies; understanding challenges in multiscale exposure data integration and identify strategies to overcome; Identify barriers to utilizing existing exposure datasets in large population studies and strategies to overcome; and to generate a review article on multiscale data integration in population studies.

The NIEHS contribution to the knowledge of gene-environment interactions will enable scientists to go beyond genetics, age, and sex to integrate factors such as stress, nutrition, immune status, and

other environmental exposures into methods to predict an individual's unique health needs and vulnerabilities. NIEHS prioritizes moving towards an understanding of collective exposure in "the exposome" and developing methods to measure and evaluate it that are as robust as the tools we currently have for the genome. Comprehensive knowledge of how genes and environment interact will position us to identify interventions and treatments with the greatest potential for maintaining and improving health.