National Toxicology Program
Director’s Report

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Director
National Institute of Environmental Health Sciences
National Toxicology Program

NTP Board of Scientific Counselors Meeting
June 20, 2018
### Appropriations Overview

<table>
<thead>
<tr>
<th></th>
<th>FY 2016 Omnibus Appropriation</th>
<th>FY 2017 Omnibus Appropriation</th>
<th>FY 2018 Omnibus Appropriation</th>
<th>FY 2019 President’s Request</th>
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<tbody>
<tr>
<td>NIEHS</td>
<td>$693,533,000(^a/)</td>
<td>$714,261,000</td>
<td>$751,143,000</td>
<td>$693,000,000</td>
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<tr>
<td>NIH (LHHS)(^c/)</td>
<td>$32,084,000,000</td>
<td>$34,084,000,000</td>
<td>$37,084,000,000</td>
<td>$34,713,000,000</td>
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<tr>
<td>Common Fund(^d/)</td>
<td>$675,639,000</td>
<td>$695,456,000</td>
<td>$600,716,000(^e/)</td>
<td>TBA</td>
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<tr>
<td>Superfund</td>
<td>$77,349,000</td>
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<td>$77,349,000</td>
<td>$54,000,000</td>
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<td>NIEHS/DOE Training</td>
<td>$10,000,000</td>
<td>$10,000,000</td>
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\(^a/\) Reduced by $169,000 transfer to the NIH Office of AIDS Research.

\(^b/\) Transfer from CDC Ebola Emergency Response appropriation to NIEHS to remain available through FY 2019.

\(^c/\) Excludes Mandatory Type 1 Diabetes Research and Superfund.

\(^d/\) Includes addition of $12.6 million for the Gabriella Miller Kids First Act pediatric research initiative.

\(^e/\) Excludes $60 million “All of US” Precision Medicine funding which the committee moved to the NIH OD.
<table>
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<tr>
<th>Activity</th>
<th>Increase</th>
<th>IC</th>
<th>Total Amount</th>
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<tr>
<td>Opioids</td>
<td>$500 million</td>
<td>NIDA &amp; NINDS</td>
<td>$500 million</td>
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<tr>
<td>Alzheimer’s</td>
<td>$414 million</td>
<td>NIA</td>
<td>$1.8 billion</td>
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<td>BRAIN</td>
<td>$140 million</td>
<td>10 ICs</td>
<td>$400 million</td>
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<tr>
<td>All of Us</td>
<td>$60 million</td>
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<td>$290 million</td>
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<tr>
<td>Antibiotic Resistance</td>
<td>$50 million</td>
<td>NIAID</td>
<td>$351 million</td>
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<tr>
<td>Universal Flu Vaccine</td>
<td>$40 million</td>
<td>NIAID</td>
<td>$100 million</td>
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<tr>
<td>Clinical and Translational Awards</td>
<td>$27.8 million</td>
<td>NCATS</td>
<td>$543 million</td>
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<tr>
<td>IDeA</td>
<td>$17.2 million</td>
<td>NIGMS</td>
<td>$351 million</td>
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<tr>
<td>Regenerative Medicine</td>
<td>$8 million</td>
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<td>$10 million</td>
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Congressional Briefing on Neurological Diseases Across the Lifespan

- Held on March 8 on the Senate side of Capitol Hill
- Avi Reichenberg, Mt. Sinai
  - Autism and Schizophrenia
- Caroline Tanner, UCSF
  - Parkinson’s Disease
- Over 60 attendees
  - 9 Senate Offices
  - 16 House Offices
  - 20+ Organizations
• ReImagine HHS launched in response to the White House Office of Management & Budget’s directive to improve efficiency and effectiveness across the government

• NIH participating in ReImagine HHS efforts to maximize effectiveness in managing data, grants, acquisitions, and hiring across the department

• NIH effort, called Optimize NIH, began in December 2017 focused on improving organizational effectiveness and performance through a thoughtful, data-driven approach
### 10 Initiative Teams Organized Under Six Strategic Shifts

<table>
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<tr>
<th>Initiative Team</th>
<th>Strategic Shift</th>
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<tr>
<td>Putting People at the Center of HHS Programs</td>
<td>Aim for Independence</td>
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<td>Restoring Market Forces</td>
<td>Accelerate Clinical Innovation</td>
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<td>Bring Common Sense to Food Regulation</td>
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<td>Leveraging the Power of Data</td>
<td>Get Better Insights from Better Data</td>
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<td>Making HHS More Innovative &amp; Responsive</td>
<td>Optimize NIH</td>
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<td>Optimize Regional Performance</td>
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<td>Optimize Coordination Across HHS</td>
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<td>Generating Efficiencies through Streamlined Processes</td>
<td>Reinvent Grants Management</td>
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<td>Buy Smarter</td>
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<td>Moving to a 21st Century Workforce</td>
<td>Maximize Talent</td>
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Optimize NIH

- **Phase 1 (underway)**: 113 volunteers from the Ethics, FOIA and Committee Management communities across the agency participating

- **Phase II (started)**: gathering metrics and assessing workload distribution across NIH in areas of scientific review, grants and program management to better manage resources in these areas; will also seek to align IC strategic plans with the NIH-wide strategic plan

- **Phase III (begins in 6-9 months)**: harmonize select administrative functions within context of virtual operational service centers and across the NIH

  - Functions will remain at the IC level, but will benefit from enhanced collaboration and adoption of best practices

  - Full *Optimize NIH* effort expected to take place over 2-3 years
NIEHS Strategic Plan independent, also supports ReImage HHS & Optimize NIH

NIEHS Leadership created a framework for the 2018-2023 Strategic Plan

- March 30: Comment period closed THANKS to NIEHSers who contributed
- March-May: Review comments and finalize plan text
- June 4-5: Present final text of plan at NAEHS Council meeting
- September 2018: Anticipated publication date
Goal 5: Identify and respond to emerging environmental threats to human health, on both a local and global scale

1. Enlist the capacity of the EHS research enterprise to elucidate information necessary for timely and effective public health action on important environmental issues of concern.

2. Act proactively with other public health partners and stakeholders to provide responses to emerging threats and emergencies, both natural and man-made.

3. Focus on EHS research areas or situations in which the current lack of knowledge hampers effective decision making and policy development.
Disaster Research Is Often Delayed or Missed

- No formal way to activate & coordinate research
- Difficulty funding research
- Slow reviews of protocols (IRB issues)
- Ethical issues and challenges not addressed
- Lack of ready-to-go research tools & protocols
- Lack of trained researchers to gather data
- Lack of inclusion of community stakeholders
- Environmental exposure data missing or not helpful
“The knowledge that is generated through well-designed, effectively executed research in anticipation of, in the midst of, and after an emergency is critical to our future capacity to better achieve the overarching goals of preparedness and response: preventing injury, illness, disability, and death and supporting recovery.”
NIH Disaster Research Response (DR2) Program

Started in 2013

1. Improved access to data collection tools for researchers

2. Faster processes (e.g., IRB, funding) for starting studies

3. Trained researchers versed in disaster tools and issues

4. Integration into planning and emergency response systems

5. Partnering with public health, academia, and impacted workers and communities

The NIH Disaster Research Response Program (DR2) is the national framework for research on the medical and public health aspects of disasters and public health emergencies. The DR2 website, provided by the National Institute of Environmental Health Sciences and the National Library of Medicine, supports disaster science investigations by offering data collection tools, research protocols, disaster research news and events, and more.

**Research Protocols**
- Protocols to collect human health data following a disaster: Pre-approved by an Institutional Review Board (IRB) for rapid use. More...
  - NIEHS RAPID Protocol
  - University of Iowa Disaster Response Research Protocol
  - UTMB Rapid Acquisition of Pre- and Post-Incident Disaster Data Protocol

**Data Collection Tools & Resources**
- Data collection tools for surveys, surveillance forms, and biospecimen and environmental sampling tools for medical and public health research in disasters. More...

**Training & Exercises**
- Training resources for preparing and making tools to conduct research in the field after a disaster.
- Exercises on data collection and research as part of disaster response and recovery, conducted by the DR2 Program. More...

**Networks, Collaborations & Partners**
- Federal agencies, private institutions, NGOs, and networks are developing their disaster-related medical and public health research capabilities. More...

**NIH Disaster Research Response Response (DR2) Website**

Rapid Acquisition of Pre/Post Incident Disaster Data (RAPIDD) Protocol

Reduce the time to initiate data collection

**Menu of standardized instruments** (select to fit the situation)
- Contact & health information, medical testing, biospecimens, etc.

**Pre-reviewed by IRB for use** (*NIEHS IRB approval May 2015*)
- IRB ethical research in disasters working group and workshop

DR2 Networks and Tabletop Exercises

Disaster Research Networks

- NIEHS Funded Research & Training Centers
- U.S. DR2 efforts: UTMB; Univ. Cincinnati, Texas A&M, OSU, IA, etc.

Training Exercises

- Los Angeles (2014) – tsunami in the Port of LA
- Houston (2015) – storm surge and flooding
- Boston (2016) – flooding East Boston & Chelsea
Efforts Paying Off: Hurricane Research Activities

NIH researchers involved within 2 weeks of Hurricane Harvey

Environmental Testing
- Testing of floodwater
  - Microbial contamination
  - Chemicals & heavy metals
- Testing of Sediments & soils

Cohort Studies (communities & workers)
- Health Impact & Mental Health Surveys
- Wrist band samples
- Home evaluations

Collaborations
- Texas A&M University
- Oregon State University
- Rice University
- University of Texas:
  - Medical Branch, Galveston
  - Houston
  - Austin
- Baylor University
- University of North Carolina at Chapel Hill
- New York University
- Mount Sinai Medical Center
Funded Time-Sensitive Research Opportunities in EHS

Hurricane Harvey

- Individual Chemical Exposures Assessments (Anderson, Oregon State University)
- Using Exposure Science to Identify Populations at Risk (Miranda, Rice University)
- Impact of Harvey on Maternal and Infant Microbiome and Birth Outcomes (Aagaard, Baylor College of Medicine)
- Environmental Health Outcomes Research in Harvey Survivors (Bondy, Baylor College of Medicine)
- Health and Resilience in a Houston Area Cohort of African-Americans with Poorly Controlled Asthma (Hamilton, Baylor College of Medicine)
- Incorporating the Microbiome into DR2 Activities (Petrosino, Baylor College of Medicine)
Hurricane Maria

- Taking a Breath After the Disaster: Homes, Mold and Health after Hurricane Maria (Cavallin, University of Puerto Rico, Rio Piedras)

- Environmental PCB Redistribution and Community Exposure (Kumar, University of Miami School of Medicine)

- Environmental Exposures and Prenatal Stress Related to Hurricane Maria among Pregnant Women: Impact on Birth Outcomes (Watkins, University of Michigan at Ann Arbor)
Wildfires, PFAS, and Others

- Wildfires & Health – Assessing the Toll on Northwest California (Hertz-Picciotto, UC Davis)
- Effects of an Extreme Wood Smoke Exposure Event in a Rural Community (Migliaccio, Univ of Montana)
- Exposure and Health Effects from PFAS in Colorado Water (Adgate, Univ of Colorado, Denver)
- Assessing Impact of Drinking Water Exposure to GenX in the Cape Fear River Basin (Hoppin, North Carolina State Univ)
- Rapid Risk Assessment of Chronic Domoic Acid Exposure in WA Razor Clam Harvesters (Grattan, Univ of Maryland, Baltimore)
- Protecting Neurodevelopment in Latino Migrant Children by Reduced Exposure to Organophosphate Pesticides (Satterwhite, Duke Univ)
• NIH Disaster Interest Group (I-DIG)
  – Monthly forum to promote disaster research, activities, and events (~65 participants from 15 ICs/programs)
  – Facilitate HHS/ASPR – "Science Preparedness” efforts
  – Sponsor annual NIH Fed. Interagency Workshop
  – White House OSTP: Subcommittee on Disaster Research

• NASEM Standing Committee on Medical and Public Health Research During Large-Scale Emergency Events
  – Funding (NIH (NIEHS, NLM, NCI, NICHD, NIAID, OBSSR), HHS, CDC, NSF, USGS)
  – Promoting disaster research priorities, processes, and implementation
  – Rapid Ebola & Zika Research Priorities Workshops
• Associations between Personal Care Product Use Patterns and Breast Cancer Risk among White and Black Women in the Sister Study.

Average body temperatures of aged male and female rats after 5 days of exposure up to 12 W/kg GSM or CDMA RFR. Studies were conducted in two cohorts, differentiated by symbols as follows: • Control, 4, 6, 8 W/kg; ○ Control, 10, 12 W/kg. *P < 0.05. † Due to animal death, only 2 or 3 time points were collected. ‡ Exposures were discontinued after day 1 due to excessive body temperature increases.
Launched April 27th!

- Updated design
- Enhanced focus on Research
- New blocks feature science resources and high interest topics
- Easier access to NIH and NIEHS lecture and seminar webcasts, webinars
- Public website: www.niehs.nih.gov
• Participating in bioRxiv (preprint server)
  – Improves submission quality
  – Convenient for authors to submit directly to EHP
  – May attract more submissions, including toxicology

• Faster publication
  – Shorter turnaround time for triage (<10 days)
  – Increased number of Associate Editors (more timely peer review)
  – Manuscripts are published throughout the month (“Continuous Publication” model).
  – Articles are posted within days of receipt of corrected proofs.

https://ehp.niehs.nih.gov
NIEHS – AAAI Foundation and Dr. William W. and Judith H. Busse Lectureship

Linda S. Birnbaum, Ph.D.
Thank You!