

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

	FY 2016 Omnibus Appropriation	FY 2017 Omnibus Appropriation	FY 2018 Omnibus Appropriation	FY 2019 President's Request
NIEHS	\$ 693,533,000 ^{a/}	\$ 714,261,000	\$ 751,143,000	\$ 693,000,000
NIH (LHHS)^{c/}	\$32,084,000,000	\$34,084,000,000	\$37,084,000,000	\$34,713,000,000
Common Fund^{d/}	\$ 675,639,000	\$ 695,456,000	\$ 600,716,000 ^{e/}	TBA
Superfund	\$ 77,349,000	\$ 77,349,000	\$ 77,349,000	\$ 54,000,000
NIEHS/DOE Training	\$ 10,000,000	\$ 10,000,000	\$ 10,000,000	

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.



FY2018 Omnibus – Targeted NIH Increases

Activity	Increase	IC	Total Amount
Opioids	\$500 million	NIDA & NINDS	\$500 million
Alzheimer's	\$414 million	NIA	\$1.8 billion
BRAIN	\$140 million	10 ICs	\$400 million
All of Us	\$60 million		\$290 million
Antibiotic Resistance	\$50 million	NIAID	\$351 million
Universal Flu Vaccine	\$40 million	NIAID	\$100 million
Clinical and Translational Awards	\$27.8 million	NCATS	\$543 million
IDeA	\$17.2 million	NIGMS	\$351 million
Regenerative Medicine	\$8 million		\$10 million



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





HHS Leadership



Alex M. Azar II
Secretary



Eric D. Hargan
Deputy Secretary



ADM Brett P. Giroir, M.D.
Assistant Secretary for Health



VADM Jerome M. Adams, M.D., M.P.H.
Surgeon General



Heather Flick
Acting Assistant Secretary
for Administration



Jennifer Moughalian
Acting Assistant
Secretary for Financial
Resources



Robert Kadlec, M.D.
Assistant Secretary for
Preparedness and Response



REIMAGINE HHS

- *Relmagine 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 *Relmagine 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



REIMAGINE HHS

10 Initiative Teams Organized Under Six Strategic Shifts



Putting People at the Center of HHS Programs

Aim for Independence



Restoring Market Forces

Accelerate Clinical Innovation

Bring Common Sense to Food Regulation



Leveraging the Power of Data

Get Better Insights from Better Data



Making HHS More Innovative & Responsive

Optimize NIH

Optimize Regional Performance

Optimize Coordination Across HHS



Generating Efficiencies through Streamlined Processes

Reinvent Grants Management

Buy Smarter



Moving to a 21st Century Workforce

Maximize Talent



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



Updating NIEHS Strategic Plan for 2018-2023

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





Emerging Global Environmental Health Threats

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

NIH National Institute of Environmental Health Sciences Your Environment. Your Health. Our Science.

Disaster Research: Challenge Areas



National Institutes of Health
U.S. Department of Health and Human Services



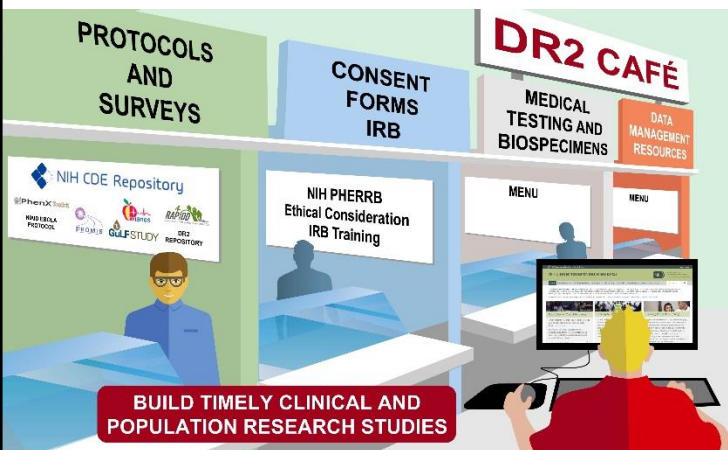
The NEW ENGLAND JOURNAL of MEDICINE

SOUNDING BOARD

Research as a Part of Public Health Emergency Response

Nicole Lurie, M.D., M.S.P.H., Teri Manolio, M.D., Ph.D., Amy P. Patterson, M.D.,
Francis Collins, M.D., Ph.D., and Thomas Frieden, M.D., M.P.H.

“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.”



5 year update to
highlight NIH progress
and activities



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**



NIH Disaster Research Response (DR2) Website

<http://dr2.nlm.nih.gov>

NIH Disaster Research Response (DR2)




National Institute of
Environmental Health Sciences
U.S. National Library of Medicine

[Home](#) [Tools/Resources](#) [Training/Exercises](#) [Research Protocols](#) [Networks](#) [Goals/Projects](#) [News/Events](#)

Site Search

New! Hurricane Disaster Research Tools
Hurricanes of 2017, from the Disaster Information Management Research Center
Researcher Deployment Guide
More resources for all types of deployment
National Science Foundation Accepting Research Proposals Related to Hurricane Harvey


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 investigators 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 RAPIDD 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...](#)


Data Collection Tools Search



Training & Exercises


Training resources for preparing scientists 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...](#)



News & Events

Upcoming events
Publications by or about the NIH Disaster Research Response Program
Past meetings, exercises, and presentations. [More...](#)



Networks, Collaborations & Partners

Federal agencies, private institutions, NGOs and networks are developing their disaster-related medical and public health research capabilities. [More...](#)



DR2 Program Goals & Projects

About the Disaster Research Response Program and efforts to address the challenging issues of disaster research. Includes Program background, a fact sheet and videos. [More...](#)

Tools & Resources

Research Protocols

Training & Exercises

Networks

Collaborations & Projects

News & Events

Funding Opportunities



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

Packenham JP, Rosselli RT, Ramsey SK, Taylor HA, Fothergill A, Slutsmann J, Miller A. Conducting Science in Disasters: Recommendations from the NIEHS Working Group for Special IRB Considerations in the Review of Disaster Related Research. *Environ Health Perspect.* 2017 Sep 25;125(9):094503. doi: 10.1289/EHP2378. PubMed PMID: 28949918.

Appendix B: Protocol Amendment Checklist

Type of Disaster	Man-made and Technological Disasters
<input type="checkbox"/> Earthquake/Tsunami	<input type="checkbox"/> Chemical release/Oil spill
<input type="checkbox"/> Flood	<input type="checkbox"/> Biological emergency
<input type="checkbox"/> Hurricane	<input type="checkbox"/> Radiological/Nuclear
<input type="checkbox"/> Tornado	<input type="checkbox"/> Explosion
<input type="checkbox"/> Wildfire	<input type="checkbox"/> Civil unrest/ war
<input type="checkbox"/> Climate Temperature Drought	<input type="checkbox"/> Utility service disruption/blackout
<input type="checkbox"/> Other _____	

Detailed description of disaster and justification for deployment: _____

III. Research Setting: _____

IV. Estimated Sample Size: _____

V. Accrual duration: _____

VI. Procedures:

<input type="checkbox"/> Visual signs	<input type="checkbox"/> Spirometry
<input type="checkbox"/> Pulse Oximetry	<input type="checkbox"/> Nail clipping collection
<input type="checkbox"/> Audiometry	<input type="checkbox"/> Saliva collection
<input type="checkbox"/> Urine collection	<input type="checkbox"/> Buccal cell collection
<input type="checkbox"/> Hair collection	<input type="checkbox"/> Hair collection
<input type="checkbox"/> Other _____	

Questionnaires (check all that will be completed during the visit):
(Provide description of procedure and list document changes and section numbers in section X of this sheet)

<input type="checkbox"/> Registry Core Form	<input type="checkbox"/> Substance Use, Abuse, Dependence
<input type="checkbox"/> General Health	<input type="checkbox"/> Exposures and Disaster Specific
<input type="checkbox"/> Mental Health	<input type="checkbox"/> Organ and Body Systems
<input type="checkbox"/> Other _____	



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.
- International: Health Canada (2016) & Japan DR2 MOU (2017)

Training Exercises

- Los Angeles (2014) – tsunami in the Port of LA
- Houston (2015) – storm surge and flooding
- Boston (2016) – flooding East Boston & Chelsea
- *Coming: Tucson (2018) – population, clinical exercise, & IRB exercise*





Efforts Paying Off: Hurricane Research Activities

NIH researchers involved within 2 weeks of Hurricane Harvey

Environmental Testing

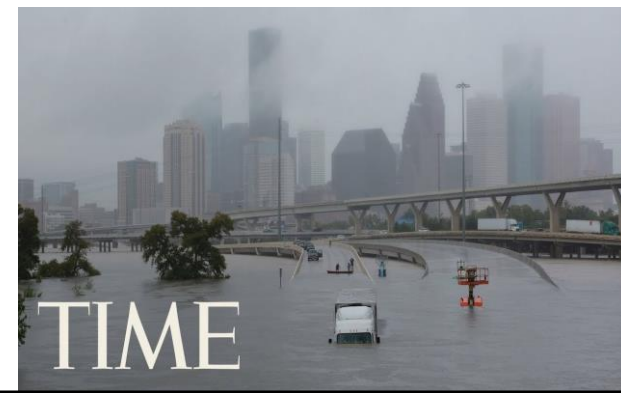
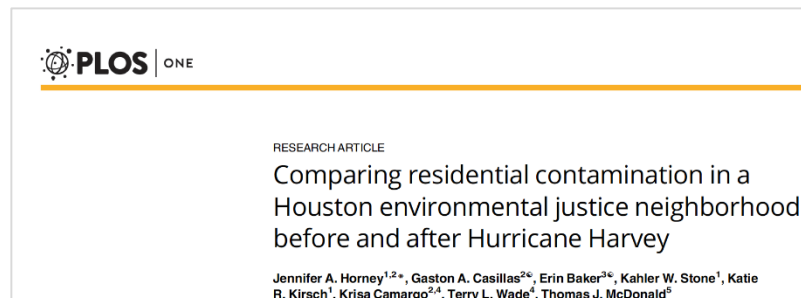
- Testing of floodwater
 - Microbial contamination
 - Chemicals & heavy metals
- Testing of Sediments & soils

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





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)





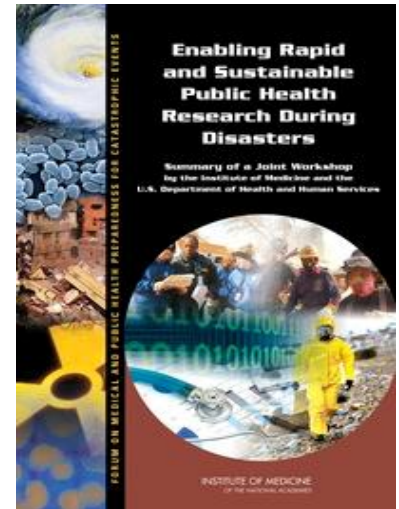
Wildfires, PFAS, and Others

- 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)



DR2 Integration, Coordination, and Engagement

- **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





One NIEHS



- **Associations between Personal Care Product Use Patterns and Breast Cancer Risk among White and Black Women in the Sister Study.**

Taylor KW [DNTP], MA Troester, AH Herring, LS Engel, HB Nichols, DP Sandler [DIR] and DD Baird [DIR].

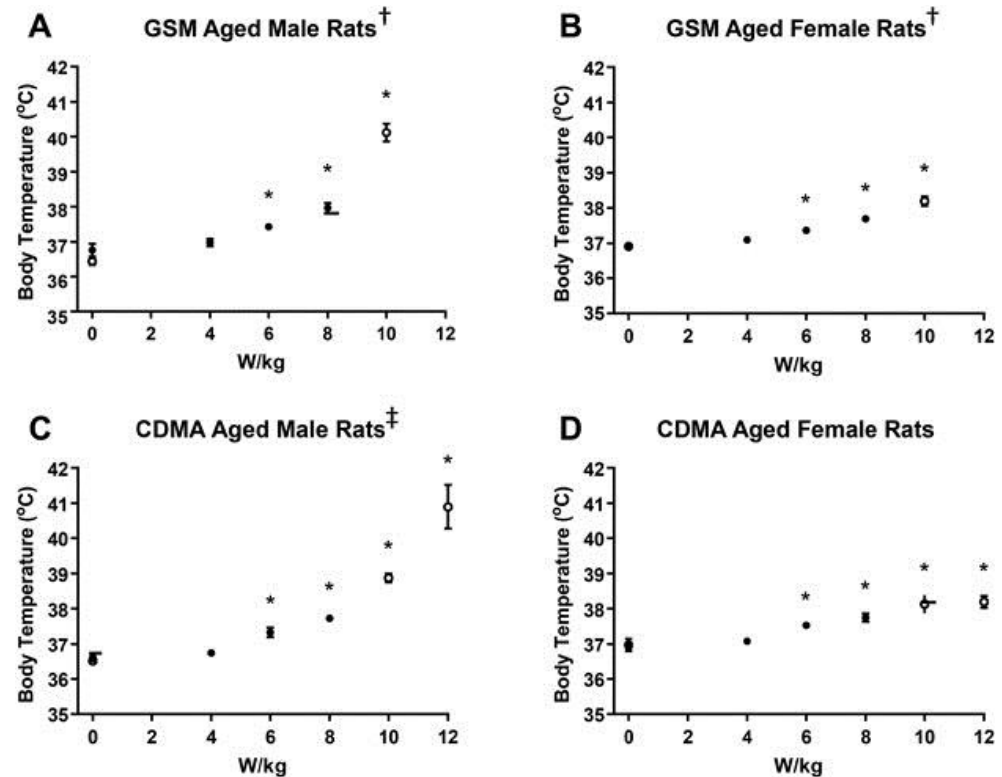
Environ Health Perspect (2018) v. 126 (2): 027011.

(SP Goal 4)



DNTP

Effect of cell phone radiofrequency radiation on body temperature in rodents: Pilot studies of the National Toxicology Program's reverberation chamber exposure system. Wyde ME [DNTP], TL Horn, MH Capstick, JM Ladbury, G Koepke, PF Wilson, **GE Kissling** [DIR], **MD Stout** [DNTP], N Kuster, RL **Melnick** [retired NTP], J Gauger, **JR Bucher** [DNTP] and DL McCormick. *Bioelectromagnetics* (2018) v. 39 (3): pp. 190-199 (SP Goals 3, 5)

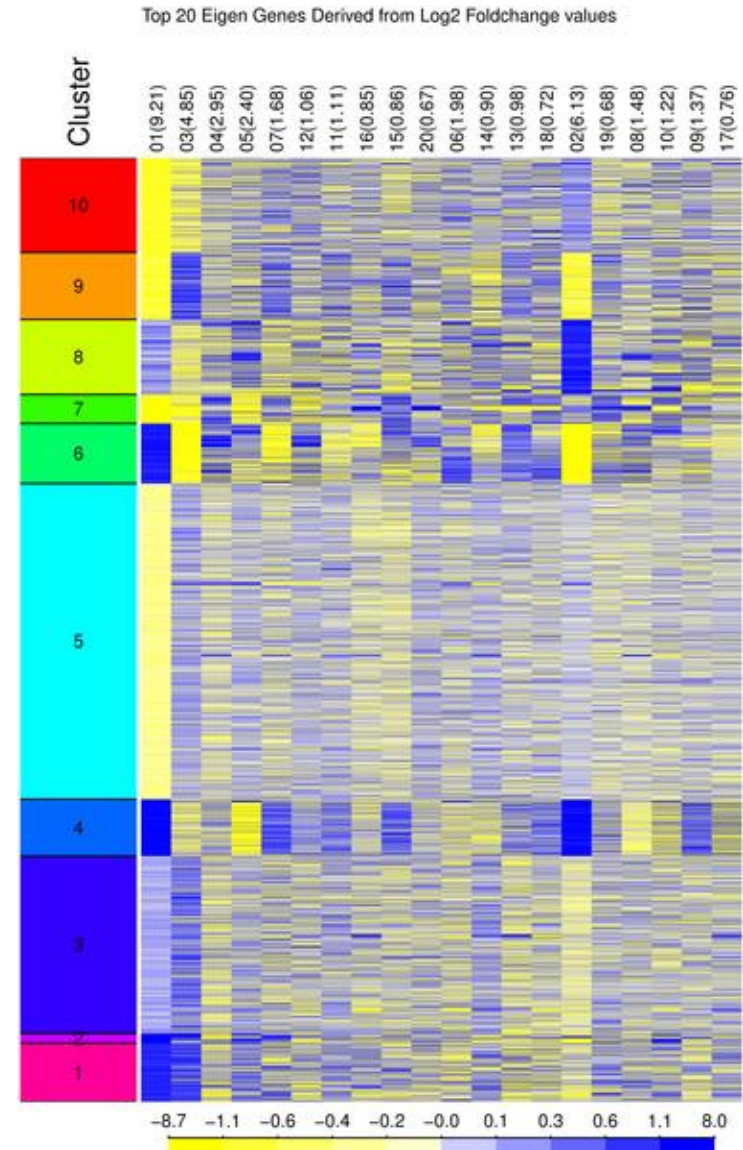


Average body temperatures of aged male and female rats after 5 days of exposure up to 12 W/kg GSM or CDMA RFR. Studies were conducted in two cohorts, differentiated by symbols as follows: • Control, 4, 6, 8 W/kg; ○ Control, 10, 12 W/kg. *P < 0.05. † Due to animal death, only 2 or 3 time points were collected.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



DNTTP

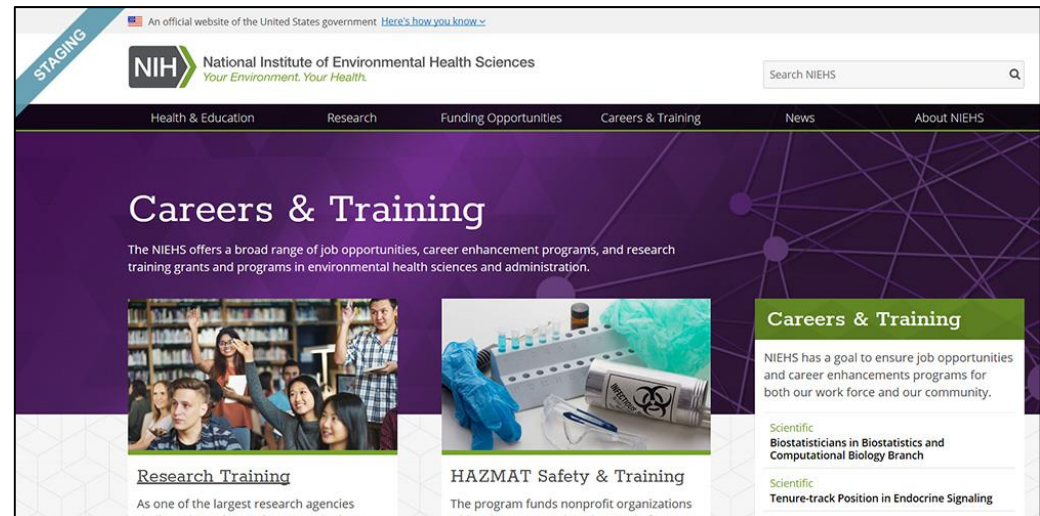
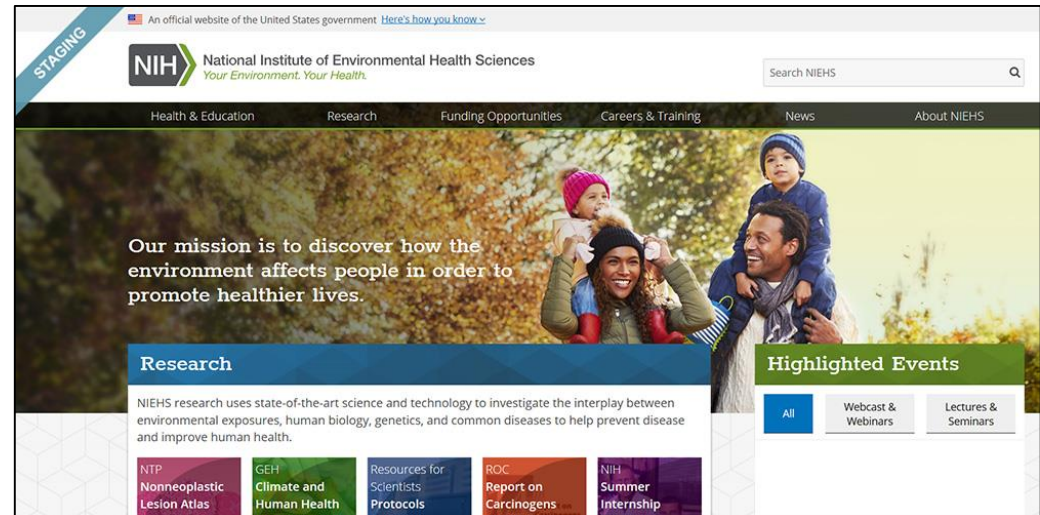
A hybrid gene selection approach to create the S1500-plus targeted gene sets for use in high-throughput transcriptomics. Mav D, Shah RR, Howard BE, Auerbach SS, Bushel PR, Collins JB, Gerhold DL, Judson RS, Karmaus AL, Maull EA, Mendrick DL, Merrick BA, Sipes NS, Svoboda D, Paules RS. *PLoS One* (2018) 13(2):e0191105. **(SP Goal 1)**





Launched April 27th!

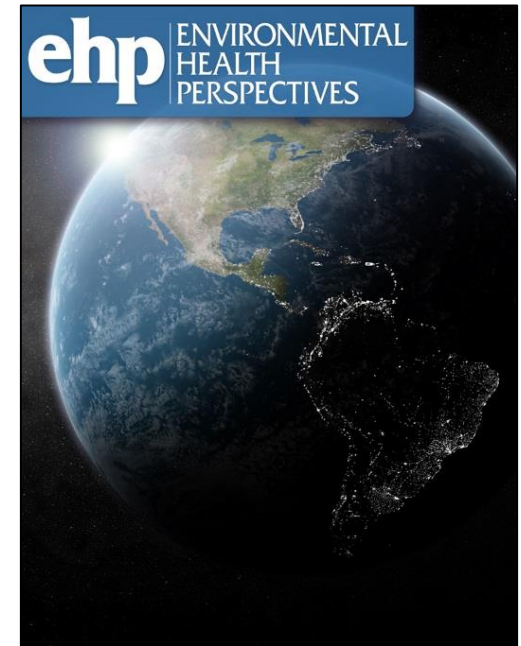
- Updated design
- Enhanced focus on Research
- New blocks feature science resources and high interest topics
- Easier access to NIH and NIEHS lecture and seminar webcasts, webinars
- Public website: www.niehs.nih.gov





What's New at EHP?

- 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>



Awards and Recognition

NIEHS – AAI Foundation and Dr. William W. and Judith H. Busse Lectureship



Linda S. Birnbaum, Ph.D.

Thank You!

