

# US EPA CSS-HERA Board of Scientific Counselors Chemical Safety Subcommittee Meeting

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US EPA CSS-HERA BOSC Meeting – February 2-5, 2021



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### **Appendix A: Chemical Safety for Sustainability**

- Part 1: Chemical Safety for Sustainability Strategic Research Action Plan, 2019 – 2022
- Part 2: CSS Scientific Portfolio Overview
- Part 3: CSS Publications
- Part 4: CSS Models, databases and tools

### **Appendix B: Human and Environmental Risk Assessment**

- Part 1: Human and Environmental Risk Assessment Strategic Research Action Plan, 2019-2022
- Part 2: HERA Scientific Portfolio Overview
- Part 3: HERA Portfolio of Delivered Products

### **Appendix C: New Approach Methods Work Plan: Reducing use of animals in chemical testing, U.S. EPA June 2020**

### **Appendix D: Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Within the TSCA Program, U.S. EPA June 2018**

## Meeting Agenda

Tuesday February 2, 2021 (connection information in Table of Contents)

| TIME (EST)   | AGENDA ACTIVITY   | PRESENTER  |
|--|---|--|
| 12:00 - 12:10  | Meeting kick off/FACA rules/expectations/logistics  | Tom Tracy, DFO, OSAPE                                    |
| 12:10- 12:15   | ORD Welcome   | Jennifer Orme-Zavaleta, ORD<br>Principal DAA for Science |
| 12:15 - 12:25  | Subcommittee Chair Opening Remarks and Introductions  | Katrina Waters, Chair                                    |
| 12:25 - 12:45  | CSS NAMs Research and Development<br>Portfolio: Connecting the Dots to Relevance and<br>Acceptance  | Jeff Frithsen, NPD, CSS                                  |
| 12:45 - 1:05   | HERA Advancing the Science and Practice<br>of Risk Assessment   | Samantha Jones, NPD, HERA                                |
| 1:05 - 1:20  | Moving from the StRAPs to Implementation by ORD<br>Investigators  | Jill Franzosa, ACD, CCTE                                 |
| 1:20 - 1:50  | Evolution of NAMs in EPA: From Research to Application  | Rusty Thomas, CD, CCTE                                   |
| 1:50 - 2:15  | BOSC Subcommittee discussion and Qs/As  | Katrina Waters, Chair                                    |
| 2:15 - 2:30  | NAMs Research Introduction with Charge Question   | Jeff Frithsen, NPD, CSS                                  |
| 2:30 – 2:45  | <b>BREAK &amp; Transition to Virtual Break-out Rooms</b>  |  |
| <b>CSS SESSION 1: CONCURRENT PRESENTATIONS ON NAMS RESEARCH</b><br><b>Note: Each research topic will be presented in 25 minutes including time for specific questions.</b> |   |  |
| 2:45 - 4:00  | <b>SESSION A: Emerging Approaches to Hazard Testing</b>   |  |
|  | 1. High Throughput Phenotypic Profiling   | Joshua Harrill, CCTE                                     |
|  | 2. High Throughput Transcriptomics  | Logan Everett, CCTE                                      |
|  | 3. Retrofitting <i>in vitro</i> Systems with Metabolic Competence   | Chad Deisenroth, CCTE                                    |
|  | <b>SESSION B: NAMs for Exposure</b>   |  |
|  | 1. High Throughput Exposure Models (SEEM)   | John Wambaugh, CCTE                                      |
|  | 2. High Throughput Toxicokinetic Models and IVIVE   | Barbara Wetmore, CCTE                                    |
|  | 3. Non-Targeted Analysis  | Jon Sobus, CCTE  |
|  | <b>SESSION C: NAMs for Ecotoxicological Applications</b>  |  |
|  | 1. Approaches and Models for Species Extrapolation  | Carlie LaLone, CCTE                                      |
|  | 2. Novel <i>in vitro</i> Methods for Ecological Species   | Brett Blackwell, CCTE                                    |
|  | 3. High Throughput Transcriptomics: A Multi-Species Approach  | Kevin Flynn, CCTE  |
|  | <b>SESSION D: System-specific Models and Approaches</b>   |  |
|  | 1. Development and Harmonization of Organotypic/Co-Culture Models and Assays to Improve Throughput and <i>In Vivo</i> Relevance in Inhaled Chemical Testing | Shaun McCullough, CPHEA                                  |
|  | 2. An Approach Using NAMs for the Evaluation of Inhalation Toxicity in OCSPP Chemical Registrations   | Mark Higuchi, CPHEA                                      |
|  | 3. Neurovascular Unit Modeling and Blood Brain Barrier Function   | Tom Knudsen, CCTE  |
| 4:00 - 5:00  | BOSC Subcommittee discussion and Qs/As  | Katrina Waters, Chair                                    |
| 5:00   | <b>ADJOURN</b>  |  |

**Wednesday February 3, 2021** (connection information in Table of Contents)

| TIME (EST)  | AGENDA ACTIVITY  | PRESENTER               |
|---|--|-------------------------|
| 12:00 - 12:10   | Public comments  | Tom Tracy, DFO, OSAPE   |
| 12:10- 12:15  | BOSC Subcommittee Chair Opening Remarks  | Katrina Waters, Chair   |
| <b>CSS SESSION 2: APPLICATIONS OF NAMs TO AGENCY AND STATE PROGRAMS</b> |  |                         |
| 12:15 - 12:30   | NAMs Applications Introduction with Charge Question  | Jeff Frithsen, NPD, CSS |
| 12:30 - 1:00  | OCSPP-TSCA Inventory: Prioritization Proof of Concept  | Richard Judson, CCTE    |
| 1:00 - 1:30   | Developmental Neurotoxicity (DNT) <i>in vitro</i> Battery as an Alternative to DNT <i>in vivo</i> Guideline Studies Used by OPP                | Tim Shafer, CCTE        |
| 1:30 - 2:00   | Implementing a Workflow for Exposure Screening of Drinking Water Contaminants of Concern   | Kristin Isaacs, CCTE    |
| 2:00 - 2:30   | Application of NAMs and AOPs to Surface Water Surveillance and Monitoring in the Great Lakes (EPA Region 5) and a Western River (EPA Region 8) | Dan Villeneuve, CCTE    |
| 2:30 – 2:45   | <b>BREAK</b>   |                         |
| 2:45 – 3:15   | BOSC Subcommittee discussion and Qs/As   | Katrina Waters, Chair   |
| <b>CSS SESSION 3: DEMONSTRATIONS OF TOOLS</b>                           |  |                         |
| 3:15 - 3:30   | NAMs Tools Demo Intro with Charge Question   | Jeff Frithsen, NPD, CSS |
| 3:30 - 4:00   | CompTox Chemicals Dashboard  | Tony Williams, CCTE     |
| 4:00 - 4:30   | SeqAPASS   | Carlie LaLone, CCTE     |
| 4:30 - 5:00   | Factotum: Curation of Exposure-Relevant Public Data  | Kristin Isaacs, CCTE    |
| 5:00 - 5:30   | BOSC Subcommittee discussion and Qs/As   | Katrina Waters, Chair   |
| 5:30  | <b>ADJOURN</b>   |                         |

**Thursday February 4, 2021** (connection information in Table of Contents)

| <b>TIME (EST)</b>   | <b>AGENDA ACTIVITY</b>   | <b>PRESENTER</b>         |
|---|--|--------------------------|
| 12:00 – 12:05   | Meeting kick off/FACA rules/expectations/logistics   | Tom Tracy, DFO, OSAPE    |
| 12:05- 12:15  | BOSC Subcommittee Chair Opening Remarks  | Katrina Waters, Chair    |
| 12:15 – 12:25   | Connecting Assessment Needs to HERA Research   | Beth Owens, PANPD, HERA  |
| 12:25 – 12:35   | ORD Implementation   | Wayne Cascio, CD, CPHEA  |
| 12:35 – 12:50   | BOSC Subcommittee discussion and Qs/As   | Katrina Waters, Chair    |
| <b>HERA SESSION 1: Applying NAMS to Inform HERA Assessments</b> |  |                          |
| 12:50 – 1:00  | Applying NAMS to Inform HERA Assessments with Charge Question                              | Luci Lizarraga, CPHEA    |
| 1:00 – 1:20   | Advancing Read-across in HERA  | Luci Lizarraga, CPHEA    |
| 1:20 – 1:40   | Filling Metabolism Data Gaps in Read-across  | Grace Patlewicz, CCTE    |
| 1:40 – 2:00   | Adverse Outcome Pathway (AOP) Footprinting for Mixtures                                    | Jason Lambert, CCTE      |
| 2:00 – 2:40   | BOSC Subcommittee discussion and Qs/As   | Katrina Waters, Chair    |
| 2:40 – 2:50   | <b>BREAK</b>   |                          |
| <b>HERA SESSION 2: Advancing Systematic Review Methods</b>      |  |                          |
| 2:50 – 3:05   | Advancing SR Methods and Tools Intro with Charge Question                                  | Kris Thayer, CPHEA       |
| 3:05 – 3:25   | Organizing and Evaluating Mechanistic Evidence   | Catherine Gibbons, CPHEA |
| 3:25 – 3:45   | Automated Data Extraction  | Michele Taylor, CPHEA    |
| 3:45 – 4:05   | Semantic Ontology Mapping  | Michelle Angrish, CPHEA  |
| 4:05 – 4:25   | Application of Systematic Evidence Map Methods to Characterize Available Evidence for PFAS | Laura Carlson, CPHEA     |
| 4:25 – 5:00   | BOSC Subcommittee discussion and Qs/As   | Katrina Waters, Chair    |
| 5:00  | <b>ADJOURN</b>   |                          |

**Friday February 5, 2021** (connection information in Table of Contents)

| <b>TIME (EST)</b>   | <b>AGENDA ACTIVITY</b>                             | <b>PRESENTER</b>                                     |
|---|--|--|
| 12:00 – 12:05   | Meeting kick off/FACA rules/expectations/logistics | Tom Tracy, DFO, OSAPE                                |
| 12:05 – 12:20   | BOSC Subcommittee Chair Opening Remarks            | Katrina Waters, Chair                                |
| <b>HERA SESSION 3: Advancing Dose-Response Analyses and Tools</b> |  |  |
| 12:20 – 12:35   | Advancing Dose-Response Intro with Charge Question | John Vandenberg, CPHEA                               |
| 12:35 – 12:55   | Multi-path Particle Dosimetry (MPPD) Model         | Annie Jarabek, CPHEA                                 |
| 12:55 – 1:15  | Bayesian Model Averaging and BMDS 3.2              | Allen Davis, CPHEA                                   |
| 1:15 – 1:35   | Approximate Probabilistic Analysis (APROBA)        | Todd Blessinger, CPHEA                               |
| 1:35 – 2:10   | BOSC Subcommittee discussion and Qs/As             | Katrina Waters, Chair                                |
| <b>CSS-HERA Closing</b>   |  |  |
| 2:10 – 2:30   | Closing Statements and Responses                   | Samantha Jones, NPD, HERA<br>Jeff Frithsen, NPD, CSS |
| 2:30 – 5:00   | BOSC Subcommittee Deliberations                    | Katrina Waters, Chair                                |
| 5:00  | <b>ADJOURN</b>                                     |  |




# BOSC Subcommittee Roster




## Designated Federal Official

### Tom Tracy




Office of Science Advisor, Policy, and Engagement  
Office of Research and Development  
U.S. EPA

## Members

|  | Name   | Affiliation  | Expertise  | Background  |
|--|--|--|--|---|
|   | (Chair)<br><a href="#">Katrina Waters, Ph.D.</a>     | Division Director, Biological Sciences Research, Pacific Northwest National Laboratory<br><br>(WA Region 10) | <ul style="list-style-type: none"> <li>• Systems biology</li> <li>• Pharmacokinetics</li> <li>• Molecular biology/genomics</li> <li>• Endocrinology</li> <li>• Bioinformatics</li> </ul>                     | Dr. Waters' expertise and research interests are focused around the analysis and biological interpretation of global gene and protein expression data related to mechanism of action or applied research. In addition, she has several years of experience developing and carrying out molecular and biochemical assays in the laboratory to test hypotheses resulting from microarray experiments.   |
|  | (Vice Chair)<br><a href="#">James Stevens, Ph.D.</a> | President, Paradox Found LLC<br><br>(NC Region 4)  | <ul style="list-style-type: none"> <li>• Computational toxicology/biology</li> <li>• High-throughput bioassays</li> <li>• Molecular toxicology</li> <li>• Pharmacology</li> <li>• Systems biology</li> </ul> | Dr. Stevens' research interests are in the areas of predictive and molecular and investigative toxicology and adverse drug reactions. He has studied the role of gene expression in mechanisms of cell injury for over two decades and was among the first to adopt gene expression analysis to understand mechanisms of toxicity. He was a member of the Board of Directors for Upstate Biotechnology and the Interim Vice President for Research and Development for Argonex Pharmaceuticals. |
|  | <a href="#">Anthony Bahinski, Ph.D., MBA, FAHA</a>   | Global Head, Safety Pharmacology, GlaxoSmithKline<br><br>(PA Region 3)                                       | <ul style="list-style-type: none"> <li>• Biology</li> <li>• Computational toxicology/biology</li> <li>• Emerging materials (nanotechnology)</li> <li>• Pharmacokinetics</li> <li>• Toxicology</li> </ul>     | Dr. Bahinski has expertise in safety pharmacology, drug discovery and development, cardiac physiology and pharmacology, and electrophysiology. His research includes the development of organ-on-a-chip technology for efficacy, safety, and toxicity evaluation of drugs, biologics, environmental toxins, and nanoparticles, including mechanistic studies and disease models. Dr. Bahinski is currently a member of the Science Board of the U.S. Food and Drug Administration.              |


|  | Name   | Affiliation   | Expertise   | Background   |
|--|--|---|---|--|
|    | <a href="#">Richard Becker, Ph.D., DABT</a>  | Senior Toxicologist, American Chemistry Council<br><br>(DC Region 3)  | <ul style="list-style-type: none"> <li>Exposure science</li> <li>Risk assessment</li> <li>Toxicology</li> </ul>   | Dr. Becker's expertise is in toxicology, risk assessment, alternatives to animal testing, prediction models, and method validation. He directs the American Chemistry Council's Long-Range Research Initiative, a research program designed to modernize and improve chemical safety assessments. Dr. Becker is a Diplomate of the American Board of Toxicology and a member of the Society of Toxicology, the American Chemical Society, and the Society for Risk Analysis.   |
|   | <a href="#">Juan Colberg, Ph.D.</a>          | Senior Director of Chemical Technology & Innovation and Green Chemistry Program Leader, Pfizer Inc. Worldwide Research and Development<br><br>(CT Region 1) | <ul style="list-style-type: none"> <li>Chemical risk assessment</li> <li>Green chemistry</li> <li>Life cycle analysis</li> <li>Risk assessment</li> <li>Sustainability</li> </ul> | Dr. Colberg's research interests are research program evaluation, chemical safety for sustainability, human health risk assessment, green chemistry, and chemical risk assessment and management. At Pfizer, he leads the chemistry technologies efforts to evaluate and develop alliances with external partners to deliver platform technologies suitable for greener and more environmentally sound chemical manufacturing of products.   |
|  | <a href="#">Richard Di Giulio, Ph.D., MS</a> | Sally Kleberg Professor of Environmental Toxicology, Duke University<br><br>(NC Region 4)   | <ul style="list-style-type: none"> <li>Biology</li> <li>Ecology</li> <li>Risk assessment</li> <li>Toxicology</li> </ul>   | Dr. Di Giulio provides expertise in environmental toxicology, ecotoxicology, and risk assessment. His research interests are the effects, including mechanisms, of environmental pollutants on aquatic organisms and humans, and on interconnections between ecological and human health. Dr. Di Giulio has fifteen years' experience directing both the Superfund Research Center and the University Program in Environmental Health at Duke University (supported by the National Institute of Environmental Health Sciences). In addition, he has eight years' experience as Co-Principal Investigator of Duke's Center for the Environmental Implications of Nanotechnology (supported by the National Science Foundation and U.S. Environmental Protection Agency). |



|  | Name  | Affiliation   | Expertise  | Background  |
|--|---|---|--|---|
|    | <a href="#">Chris Gennings, Ph.D.</a>               | Research Professor, Icahn School of Medicine at Mount Sinai<br><br>(NY Region 2)  | <ul style="list-style-type: none"> <li>Information science</li> <li>Human health risk assessment (chemical mixtures risk assessment)</li> </ul>            | Dr. Gennings' research interests focus on chemical mixtures risk assessment including developing and implementing statistical techniques useful for estimating risk assessment of exposure to combinations of chemicals; designing economical study designs for mixtures of many chemicals; statistical modeling of pesticide mixtures; and integration of mixtures toxicology and statistics. She is the founding director of a T32 training grant from the National Institute of Environmental Health Sciences (NIEHS) in Environmental Statistics, focused on the integration of mixtures toxicology and statistical methods. Her research has been supported by NIEHS, U.S. Environmental Protection Agency, World Health Organization, National Institute of Child Health and Human Development, and the Health Effects Institute. |
|   | <a href="#">Dale Johnson, Pharm.D., Ph.D., DABT</a> | President and CEO, Emiliem, Inc.;<br>Adjunct Professor, University of Michigan; Adjunct Professor, University of California, Berkeley<br><br>(MI Region 5, CA Region 9) | <ul style="list-style-type: none"> <li>Computational toxicology/biology</li> <li>Pharmacokinetics</li> <li>Risk assessment</li> </ul>                      | Dr. Johnson has technical expertise in computational toxicology and quantitative structure-activity relationship (QSAR) modeling. At the University of California, Berkeley, Dr. Johnson's research focuses on predictive toxicology and network pharmacology utilizing computational methodology to analyze chemical-biological interactions, model structure activity relationships, and analyze perturbations in systems biology pathways.   |
|  | <a href="#">Daland Juberg, Ph.D., ATS</a>           | Human Health Science Policy Leader, Corteva<br><br>(IN Region 5)  | <ul style="list-style-type: none"> <li>Toxicology</li> <li>Exposure science</li> <li>Public health (children's health)</li> <li>Risk assessment</li> </ul> | Dr. Juberg has expertise in public health, toxicology, children's health, exposure science, risk assessment, sustainability, science policy, and risk communication. He has diverse industrial sector and consulting experiences spanning a number of scientific disciplines that are central to the evaluation and protection of human health and the environment. Dr. Juberg is an active member of the Society of Toxicology and a Fellow of the Academy of Toxicological Sciences.  |

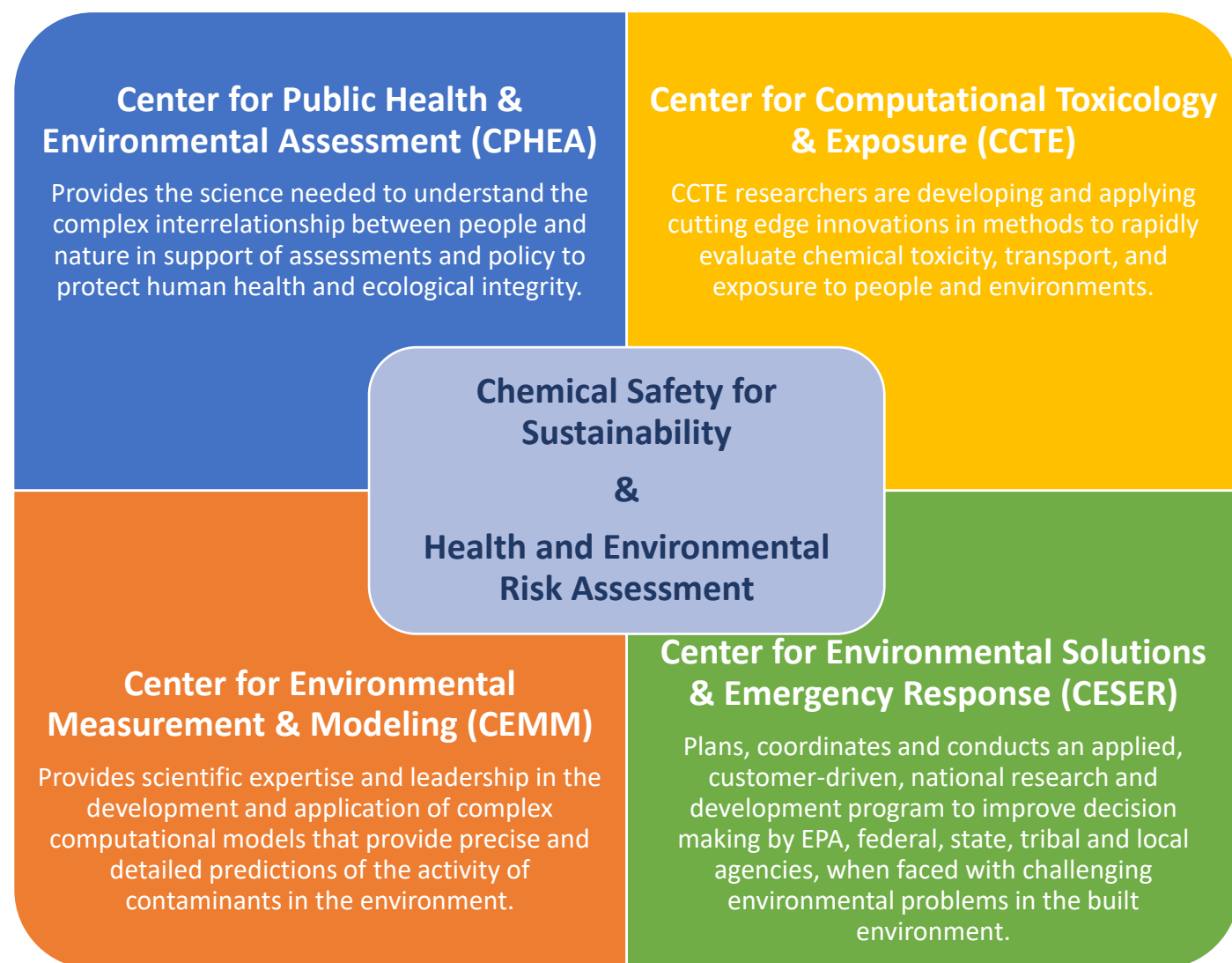
|  | Name                                       | Affiliation   | Expertise   | Background  |
|--|--|---|---|---|
|    | <a href="#">Juleen Lam, Ph.D., MHS, MS</a> | Assistant Professor, California State University, East Bay<br><br>(CA Region 9) | <ul style="list-style-type: none"> <li>• Epidemiology</li> <li>• Human health risk assessment</li> <li>• Public health</li> <li>• Risk assessment</li> <li>• Toxicology</li> </ul>  | Dr. Lam has expertise in environmental health, environmental health policy, biostatistics, systematic review, and risk assessment. One key area of her research involves the development, improvement, and implementation of evidence-based systematic review methodology tailored specifically for use in environmental health to inform science-based policy- and decision-making. Her other research interests include advancing quantitative tools in risk assessment as well as the incorporation of high throughput screening approaches to predicting human toxicity. Dr. Lam has previously worked with the U.S. Environmental Protection Agency in the Office of Policy.                             |
|   | <a href="#">Timothy Malloy, J.D.</a>       | Professor, University of California, Los Angeles<br><br>(CA Region 9)           | <ul style="list-style-type: none"> <li>• Decision science/analysis/value of information</li> <li>• Public health</li> <li>• Risk assessment</li> <li>• Social science</li> <li>• Toxicology</li> <li>• Behavioral science (risk communication)</li> </ul> | Mr. Malloy's research interests include the application of science and engineering in regulatory and business settings, including nanotechnology, emerging materials, public health, risk assessment, sustainability, toxicology, law and social science, and decision science. One aspect of his research deals with the value and limits of applying decision analysis to public and private decisions regarding identification and evaluation of safer chemicals.  |
|  | <a href="#">Jennifer McPartland, Ph.D.</a> | Senior Scientist, Environmental Defense Fund<br><br>(DC Region 3)               | <ul style="list-style-type: none"> <li>• Biology</li> <li>• Chemical risk assessment</li> <li>• Computational toxicology/biology</li> <li>• High-throughput bioassays</li> <li>• Toxicology</li> </ul>  | Dr. McPartland works to identify and reduce chemical exposures harmful to human health and the environment. Her work at Environmental Defense Fund includes science, policy, and marketplace-related initiatives. In each of these areas, Dr. McPartland works with diverse groups of stakeholders to determine how improvements can be made to understand and ultimately reduce or eliminate toxic chemical exposures. Dr. McPartland has focused on new computational toxicology methods being developed by the U.S. Environmental Protection Agency to better understand and predict chemical hazard and risk, as well as efforts by the agency to apply systematic review methods in chemical assessment. |
|  | <a href="#">Jane Rose, Ph.D.</a>           | Principal Scientist, Procter and Gamble Company<br><br>(OH Region 5)            | <ul style="list-style-type: none"> <li>• Human health risk assessment</li> <li>• Risk assessment</li> <li>• Toxicology</li> </ul>   | Dr. Rose has expertise in chemical risk assessment, inhalation toxicology exposure assessments, and the development of threshold of toxicological concern approaches. She has established inhalation exposure modeling approaches for consumer products and integrated these approaches into the industry aggregate exposure framework. Dr. Rose is also the leader of the Inhalation Safety Expert Team at The Procter and Gamble Company.   |

|   | Name   | Affiliation   | Expertise  | Background   |
|---|--|---|--|--|
|    | <a href="#">Gina Solomon, M.D., MPH</a>            | Principal Investigator, Public Health Institute; Clinical Professor, University of California, San Francisco<br><br>(CA Region 9) | <ul style="list-style-type: none"> <li>• Endocrinology</li> <li>• Environmental health sciences</li> <li>• Public health (children's health)</li> <li>• Risk assessment</li> </ul> | Dr. Solomon has experience working for a non-governmental organization, hospitals, a research institute, and universities. She addresses technical issues as well as policy. Dr. Solomon's prior work has included research on diesel exhaust and asthma, endocrine disrupting chemicals, pesticides, environmental contaminants in New Orleans after Hurricane Katrina, the health implications of the 2010 Gulf oil spill, and the health effects of climate change. |
|   | <a href="#">Ponisseril Somasundaran, Ph.D., MS</a> | President, Somasundaran, Inc.; La von Duddleson Krumb Professor, Columbia University<br><br>(NY Region 2)                         | <ul style="list-style-type: none"> <li>• Emerging materials</li> <li>• Toxicology</li> </ul>   | Dr. Somasundaran has expertise in green chemistry, energy, waste water treatment, and nanotoxicity/environmental effects of nanoparticles. He specializes in surface and colloid chemistry. His research has been concerned with a wide spectrum of environmental problems including greener chemistry, enhanced oil recovery, remediation, tar sands, coal cleaning, sludge treatment, waste water treatment, and nanotoxicity.                                       |
|  | <a href="#">Donna Vorhees, Sc.D.</a>               | Director of Energy Research, Health Effects Institute; Adjunct Assistant Professor, Boston University<br><br>(MA Region 1)        | <ul style="list-style-type: none"> <li>• Exposure science</li> <li>• Human health risk assessment</li> </ul>   | Dr. Vorhees specializes in multi-pathway exposure assessment and human health risk assessment of chemicals in indoor and outdoor environments. She has 20 years of consulting experience and has conducted deterministic and probabilistic exposure and risk modeling for chemicals, such as polychlorinated biphenyls, dioxins and furans, petroleum hydrocarbons, volatile organic compounds, and metals (e.g., arsenic, lead, and mercury).                         |
|  | <a href="#">Clifford P. Weisel, Ph.D.</a>          | Professor, Exposure Science, Environmental and Occupational Health Sciences Institute, Rutgers University<br><br>(NJ Region 2)    | <ul style="list-style-type: none"> <li>• Exposure science</li> <li>• Human health risk assessment</li> </ul>   | Dr. Weisel's research experience includes the determination of biomarkers of exposure, measurement of multiroute exposures to volatile organic compounds and disinfection byproducts in drinking water, exposure to children, the role of air pollution in exacerbation of asthma, exposures within modes of transportation, the sources of pollutants to indoor air and their contribution to personal exposure, and the how exposures affect the lung microbiome.    |

|  | Name                                | Affiliation  | Expertise  | Background   |
|--|-------------------------------------|--|--|--|
|  | <a href="#">Mark Wiesner, Ph.D.</a> | <p>James B. Duke Professor of Civil and Environmental Engineering, Duke University;<br/> Chair, Department of Civil and Environmental Engineering, Duke University;<br/> Director, Center for the Environmental Implications of NanoTechnology (CEINT)</p> <p><i>(NC Region 4)</i></p> | <ul style="list-style-type: none"> <li>Emerging materials</li> </ul> | <p>Dr. Wiesner's research interests include membrane processes, nanostructured materials, transport and fate of nanomaterials in the environment, colloidal and interfacial processes, and environmental systems analysis. Dr. Wiesner's research pioneered the application of membrane processes to environmental separations and water treatment. He co-edited and -authored the book <i>Water Treatment Membrane Process</i>, and served as the founding Chair of the American Water Works Association's Membrane Research Committee. He also co-edited and -authored the book <i>Environmental Nanotechnologies</i>.</p> |

## Office of Research and Development

Within the EPA's Office of Research and Development, the national research programs partner with the ORD centers to carry out the research outlined in the StRAP.



## Office of Research and Development Center Leadership

### Immediate Office of the Assistant Administrator

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## CSS National Research Program Review Charge Questions

**Introduction:** The February 2021 meeting of the CSS-HERA Subcommittee of the Board of Scientific Counselors (BOSC) will review that portion of the CSS portfolio involved in the development and application of New Approach Methodologies (NAMs). The focus of the review is on the implementation of research and development that was outlined at the strategic level in the CSS Strategic Research Action Plan for FY19-22, as previously reviewed by the BOSC.

### ***Charge Question 1***

The CSS portfolio advances New Approach Methods (NAMs) across multiple research areas related to chemical evaluation and risk assessment. CSS Session 1 presents selected research activities to highlight NAMs development for hazard evaluation, exposure, ecotoxicology, and human-system models. Please provide specific suggestions or recommendations to improve approaches to advance the development and testing of NAMs conducted under the CSS program.

### ***Charge Question 2***

A key long-term objective of the CSS program is to increase the pace of chemical assessment through the incorporation of NAMs into decision making by EPA programs and regions and other stakeholders. CSS Session 2 presents examples of NAMs implementation that address specific, articulated needs of Agency partners. Please comment on the extent to which these selected research activities have the appropriate approach, structure, and components to increase confidence in, and to facilitate use of, NAMs in Agency decision making.

### ***Charge Question 3***

CSS continues to develop and evolve multiple publicly-available data resources, analytical tools, and predictive models to facilitate the dissemination and use of chemical-safety information tailored to meeting specific user's needs. The long-term intent is for these CSS-supported platforms to provide a comprehensive resource to support the needs of our partners. CSS Session 3 presents examples of CSS information resources, models, and tools. Please provide suggestions or recommendations regarding how these CSS products can be improved and best implemented to serve EPA partners and external stakeholders?

## HERA National Research Program Review Charge Questions

### ***Charge Question 1:***

As NAMs' science advances, risk assessors still encounter many chemicals with little-to-no data that require assessment. Research is required to translate and build confidence in the application of these NAMs in HERA science assessment contexts. Building on the case study examples, please provide suggestions or recommendations on how the planned research can best advance the integration of NAM data streams and approaches in HERA science assessments. [Research Area 3, Output 3.1]

### ***Charge Question 2:***

Incorporating the principles of systematic review into the HERA portfolio of assessment products has been a goal of the HERA program for the last several years. In order to achieve this goal, the HERA program intends to advance the field of systematic review more broadly. Based on the progress to date and currently planned products, what suggestion(s) or recommendation(s) does the Subcommittee offer on HERA's research to advance methods for systematic review? [Research Area 3, Output 3.4]

### ***Charge Question 3:***

Dose-response modeling is a critical step in human health assessment. Existing methods have improved upon older methodologies; however, unresolved issues, uncertainties, and complications remain that require targeted research. HERA has planned research products that will result in dose-response methods that are more precise, robust, and meet varied needs. Noting the examples provided, please comment on the extent to which these planned products address important issues in dose-response modeling for application to risk assessment, and ways this research might be augmented? What suggestion(s) or recommendation(s) does the Subcommittee offer to continue to advance methods in dose-response modeling with an application to risk assessment? [Research Area 3, Output 3.5 and Research Area 4, Output 4.1]

## CSS STAR Extramural Research Program

The Science to Achieve Results (STAR) Program is EPA's primary competitive, peer-reviewed, extramural research program. It funds nationally relevant research, leverages a wide variety of scientific and engineering resources, and provides collaborative access to innovative academics. Requests for Application (RFAs) originate in the EPA Office of Research and Development in cooperation with other Agency offices.

The **Safer Chemicals Research** grants align with the core mission of EPA's Chemical Safety for Sustainability (CSS) National Research Program to make informed and timely decisions concerning potential impacts of environmental chemicals on human health and the environment. A selection of recent Safer Chemicals Research RFAs is included below.

### [Assessment Tools for Biotechnology Products](#) (FY2020 RFA)

Awards forthcoming

### [Advancing Toxicokinetics for Efficient and Robust Chemical Evaluations](#) (FY2019 RFA)

Integrated blood brain barrier-computational model development to predict doses of concern for compound linked neurotoxicity

Purdue University 2020-2023

Measuring Toxicokinetics for Organ-on-Chip Devices

Vanderbilt University 2020-2023

Integrating tissue chips, rapid untargeted analytical methods and molecular modeling for toxicokinetic screening of chemicals, their metabolites and mixtures

Texas A&M University 2020-2023

Toxicokinetic screening of zebrafish cytochrome P450 enzymes for in vitro-in vivo extrapolation

Woods Hole Oceanographic Institution 2020-2023

An in vitro-in silico hybrid approach for high-throughput estimation of trans-barrier permeability for chemical pollutants

University of Nevada – Reno 2020-2023

### [Advancing Actionable Alternatives to Vertebrate Animal Testing for Chemical Safety Assessment](#) (FY2018 RFA) (*Focus on New Approach Methodologies (NAMs)*)

Skeletal Teratogenicity of Industrial and Environmental Chemicals Predicted with Human Pluripotent Stem Cells in Vitro

University of California – Riverside 2019-2022

A Neurovascular Unit on Chip for Reducing Animals in Organophosphate Neurotoxicology

Vanderbilt University 2019-2022

Instrumenting phenotypic immunological responses to toxicants that threaten human reproduction

Vanderbilt University Medical Center 2019-2022

Multiplexed human BrainSphere Developmental Neurotoxicity Test for Six Key Events of Neural Development  
The Johns Hopkins University 2019-2022

Reducing the reliance on early-life stage testing with relevance to euryhaline fishes: Development and implementation of in-vitro assays predictive of early life stage toxicity and population-level effects in *Menidia beryllina*  
Louisiana State University, Oregon State University 2019-2022

[Systems-Based Research for Evaluating Ecological Impacts of Manufactured Chemicals](#) (FY2014 RFA)  
Integrated Modeling Approaches to Support Systems-Based Ecological Risk Assessment  
Harvard University, President and Fellow of Harvard College, Washington State University 2015-2018

System Toxicological Approaches to Define Flame Retardant Adverse Outcome Pathways  
Oregon State University 2015-2019

A Bioenergetics-Based Approach to Understanding and Predicting Individual- to Community-Level Ecological Effects of Manufactured Chemicals  
Towson University 2015-2020

Development of a larval fish neurobehavior adverse outcome pathway to predict effects of contaminants at the ecosystem level and across multiple ecologically relevant taxa  
Michigan State University 2015-2021

Linking Biological Scales Across Generations: An Estuarine and Marine Model for Measuring the Ecological Impact of Endocrine Disrupting Compounds  
Oregon State University 2015-2020

Dynamical Systems Models Based on Energy Budgets for Ecotoxicological Impact Assessment  
University of California – Santa Barbara 2015-2019

[Organotypic Culture Models for Predictive Toxicology Center](#) (FY2013 RFA) (*Focus on Organs on a Chip*)  
Human Models for Analysis of Pathways (H MAPs) Center  
University of Wisconsin Madison 2014-2019

Cardiotoxicity Adverse Outcome Pathway: Organotypic Culture Model and in vitro- to in-vivo Extrapolation for High-throughput Hazard, Dose-response and Variability Assessments  
Texas A&M University 2015-2021

Predictive Toxicology Center for Organotypic Cultures and Assessment of AOPs for Engineered Nanomaterials  
University of Washington 2014-2020

Vanderbilt-Pittsburgh Resource for Organotypic Models for Predictive Toxicology  
University of Pittsburgh, Vanderbilt University 2014-2019

Full listing of [Safer Chemicals Research grants](#)

## CSS Highlights and Notable Accomplishments

2019 - Present

### Top 14 Most Published in Journals

| Title   | Journal Impact Factor | # of CSS Publications |
|---|-----------------------|-----------------------|
| 1. <i>Toxicological Sciences</i>  | 3.703                 | 32                    |
| 2. <i>Environmental Toxicology and Chemistry</i>                        | 3.152                 | 25                    |
| 3. <i>Environmental Science &amp; Technology</i>                        | 7.864                 | 18                    |
| 4. <i>Science of the Total Environment</i>                              | 6.551                 | 12                    |
| 5. <i>Computational Toxicology</i>                                      | 2.11                  | 11                    |
| 6. <i>Toxicology in Vitro</i>   | 2.959                 | 9                     |
| 7. <i>Environmental Health Perspectives</i>                             | 8.341                 | 8                     |
| 8. <i>Regulatory Toxicology and Pharmacology</i>                        | 2.652                 | 8                     |
| 9. <i>Environmental Science: Nano</i>                                   | 7.683                 | 7                     |
| 10. <i>Aquatic Toxicology</i>   | 4.346                 | 6                     |
| 11. <i>Analytical and Bioanalytical Chemistry</i>                       | 3.637                 | 6                     |
| 12. <i>Journal of Exposure Science &amp; Environmental Epidemiology</i> | 3.531                 | 6                     |
| 13. <i>Chemosphere</i>  | 5.778                 | 6                     |
| 14. <i>PLoS ONE</i>   | 2.74                  | 6                     |

### Total Number of Publications

| 2019 | 2020 | 2021 (as of 1/14/2021) |
|------|------|------------------------|
| 153  | 133  | 13                     |

## CSS Publications Receiving External Recognition

### **Society of Toxicology's Best Postdoctoral Publication Award, 2021**

Nyffeler J, Willis C, Lougee R, et al. (2020). [Bioactivity screening of environmental chemicals using imaging-based high-throughput phenotypic profiling](#). *Toxicol Appl Pharmacol*, 389, 114876.

### **American Chemical Society Editor's Choice Award, November 2020**

Richard AM, Huang R, Waidyanatha S, et al. (2020). [The Tox21 10K Compound Library: Collaborative Chemistry Advancing Toxicology](#). *Chem Res Toxicol*.

### **The Society of Environmental Toxicology and Chemistry Exceptional Paper Award, June 2020**

Villeneuve DL, Coady K, Escher BI, et al. (2019). [High-throughput screening and environmental risk assessment: State of the science and emerging applications](#). *Environ Toxicol Chem*, 38(1), 12-26.

### **Computational Toxicology Specialty Section of the Society of Toxicology, Paper of the Year, 2019**

#### **Toxicological Sciences Paper of the Year: Honorable Mention, 2019**

Wambaugh JF, Hughes MF, Ring CL, et al. (2018). [Evaluating In Vitro-In Vivo Extrapolation of Toxicokinetics](#). *Toxicol Sci*, 163(1), 152-169.

### **Best Paper Advancing the Science of Risk Assessment, from the Risk Assessment Specialty Section of the Society of Toxicology, 2018**

Phillips KA, Wambaugh JF, Grulke CM, et al. (2017). [High-throughput screening of chemicals as functional substitutes using structure-based classification models](#). *Green Chemistry*, 19(4), 1063-1074.

### **International Society of Exposure Science Award for Best Journal of Exposure Science and Environmental Epidemiology Paper, 2018**

Morgan MK, MacMillan DK, Zehr D, Sobus JR (2018). [Pyrethroid insecticides and their environmental degradates in repeated duplicate-diet solid food samples of adults](#). *J Expo Sci Environ Epidemiol*, 28, 40-45.

### **Included in the Best of the Journal of Exposure Science and Environmental Epidemiology 2018-2019 Special Collection**

Sobus JR, Wambaugh JF, Isaacs KK, et al. (2018). [Integrating tools for non-targeted analysis research and chemical safety evaluations at the US EPA](#). *J Expo Sci Environ Epidemiol*, 28, 411-426.

## CSS Investigators Receiving External Recognition

### **The Society of Toxicology's Enhancement of Animal Welfare Award, 2021**

*In recognition of contributions made to the advancement of toxicological science through the development and application of methods that replace, refine, or reduce the need for experimental animals.*

Dr. Barbara Wetmore                      Center for Computational Toxicology and Exposure

### **LUSH Prize for Young Investigators, 2020**

*Supporting initiatives to end or replace animal testing.*

Project: High-throughput phenotypic profiling of human neural progenitor cells to identify putative modes-of-action of developmental neurotoxicants

Dr. Johanna Nyffeler                      Center for Computational Toxicology and Exposure

### **Presidential Early Career Award for Scientists and Engineers (PECASE) Award, 2019**

*The highest honor bestowed by the U.S. government on outstanding scientists and engineers beginning their independent careers.*

Dr. Carlie LaLone                      Center for Computational Toxicology and Exposure

Dr. Jon Sobus                      Center for Computational Toxicology and Exposure

### **SETAC Presidential Citation for Exemplary Service, 2018**

*For planning and chairing the SETAC North America Focused Topic Meeting "High Throughput-Screening and Environmental Risk Assessment"*

Dan Villeneuve                      Center for Public Health and Environmental Assessment