



OFFICE OF THE SCIENCE ADVISOR
ENVIRONMENTAL PROTECTION AGENCY

2016 Annual Report

LETTER FROM THOMAS BURKE, EPA SCIENCE ADVISOR

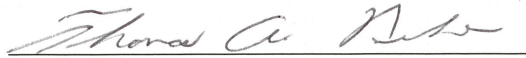


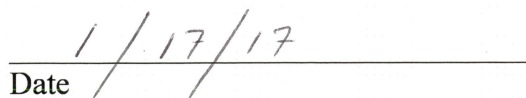
Science is a keystone in the foundation that supports the Environmental Protection Agency. Science is dynamic. New discoveries are constant and our understanding of complex issues changes over time. Scientific discovery, knowledge, translation, implementation, and uncertainty are all fundamental to the scientific process. At EPA we focus on using the best science to form our understanding of how to protect people and the environment. Accurate scientific information lets us know the severity of environmental hazards, the people at risk, and how best to prevent adverse events and improve health and the environment. Accurate scientific information is important not only when we respond to an emergency, but also to prevent disease and protect the environment in years to come.

The EPA Science Advisor plays an essential role within the agency. The Science Advisor is also the leader of the Agency's Office of Research and Development which conducts applied environmental and human health research that will inform program and regional decisions in the future. This research depth is critical for the Science Advisor to align available resources and expertise with program and regional needs or when asked to respond to National or local emergencies. The Science Advisor also promotes Agency-wide science policies that are intended to harmonize science practices and policies across the Agency. The Office of the Science Advisor (OSA) supports this aspect of the Science Advisor's role. OSA supports the Science and Technology Policy Council (STPC) and its standing groups that promote uniform practices for risk assessment, environmental measurements, our laboratory enterprise, and peer review practices. OSA also implements the agency's policies and practices for scientific integrity and human subjects research protection.

This past year has been filled with accomplishments and challenges for OSA. We finalized EPA's *Plan to Increase Access to EPA-funded Research Results* and implemented the plan for all ORD intramural research published in 2016. We completed EPA's first Strategic Foresight Planning Pilot; released Best Practices for Designating Authorship; and trained thousands of EPA staff on scientific integrity, human subjects research protections, and peer review policies. We have also revised our charters for the STPC and the Risk Assessment Forum. This effort should result in greater oversight by the STPC in selecting and approving projects. Revised review procedures and enhanced project tracking should result in better products that are completed faster and have more impact across the Agency.

It has been a privilege to work with the OSA staff, who have supported me in my role as the Science Advisor. This dedicated team has made my job easier and the Agency stronger. Thank you all for the hard work that you do.


Thomas A. Burke, Ph.D., MPH


Date

OFFICE OF THE SCIENCE ADVISOR IN 2016

AT A GLANCE

The Office of the Science Advisor (OSA) supports the US Environmental Protection Agency's (EPA or the Agency) Science Advisor (SA). We do this by:

- identifying, addressing, and implementing cross-Agency science and technology policy issues;
- overseeing human subjects research protections; and
- implementing the EPA Scientific Integrity Policy.

This is the first annual report issued by OSA. It summarizes 2016 fiscal and calendar year accomplishments, on-going activities, and new initiatives.

OSA assembles Agency experts to formulate policy, guidance and strategies to improve and harmonize science-related activities across the Agency's offices, programs, and regions. These may be approved, adopted, and implemented by the Science and Technology Policy Council (STPC), a cross agency decision-making body whose members are senior agency career leaders. Our work is accomplished through standing groups that promote coordination of a scientific or technical issue having broad and long term implications across the Agency. OSA supports the Risk Assessment Forum (RAF), the Laboratory Enterprise Forum (LEF), the Peer Review Advisory Group (PRAG), and the Forum on Environmental Measurements (FEM). The standing groups OSA supports do not conduct scientific research or conduct program specific activities (e.g., the RAF does not produce risk assessments).

Within OSA, the Scientific Integrity Official and the Human Subjects Research Review Official coordinate, harmonize, and champion EPA's scientific integrity and human subject research protection practices. Scientific integrity and human subjects research are guided by specific policies and OSA assists in their implementation.

OSA manages two of EPA's Federal Advisory Committees, the Human Studies Review Board (HSRB) and the Environmental Laboratory Advisory Board (ELAB).

OSA also is called upon to take on new or emerging science policy issues that require cross-Agency attention.

OSA 2016 HIGHLIGHTS

- Completing EPA's [*Plan to Increase Access to EPA-funded Research Results*](#).
- Releasing [*The Fourth Edition of EPA's Peer Review Handbook*](#).
- Conducting trainings for thousands of EPA staff on Peer Review, Human Subjects Protection, and Scientific Integrity.
- Releasing EPA's first set of [*Best Practices for Designating Authorship*](#).
- Releasing four Risk Assessment Forum products.
- Launching EPA's Laboratory Enterprise Forum.
- Completing EPA's Strategic Foresight Pilot project.

HISTORY OF OSA AND ITS PROGRAMS

1991 – EPA adopts the Common Rule, which protects human subjects during research.

1993 – the Science Policy Council is created to address significant issues that go beyond regional or program boundaries.

1993 – the Risk Assessment Forum (RAF) is established to harmonize Agency-wide approaches on difficult and controversial risk assessment issues.

1995 – Environmental Laboratory Advisory Board (ELAB) is established to gather consensus advice from the environmental measurement community.

1999 – EPA creates a part- time Human Subjects Research Review Official (HSRRO) position.

2003 – the Office of the Science Advisor (OSA) is established with Paul Gilman as the Science Advisor.

2003 – the Forum on Environmental Measurements (FEM) is established to promote consistency and consensus in EPA on measurement issues.

2004 – the Peer Review Advisory Group (PRAG) is initially formed.

2005 – George Gray becomes Science Advisor.

2006 – EPA changes the HSRRO position to be full time.

2006 –The Human Studies Review Board (HSRB) is created to review and comment on proposed and completed third-party pesticide or disinfection research.

2009 – Paul Anastas becomes Science Advisor.

2010 – the Science Policy Council becomes the Science and Technology Policy Council (STPC).

2010 – the PRAG is reactivated.

2012 – Glenn Paulson becomes Science Advisor.

2012 – The Scientific Integrity Policy is released, creating the Scientific Integrity Committee and the position of the Scientific Integrity Official.

2014 – Tom Burke becomes the Science Advisor.

2015 – The Laboratory Enterprise Forum (LEF) is established to improve collaboration across the Agency's laboratory enterprise.

ACKNOWLEDGEMENTS

The 2016 Office of the Science Advisor Annual Report was written, edited, reviewed, and released by the Office of the Science Advisor. This is the first annual report released by OSA. It provides EPA colleagues and stakeholders concise information about what OSA is and what it does. It is a companion to the Annual Report on Scientific Integrity released by the Agency's Scientific Integrity Official. The OSA Annual Report summarizes 2016 calendar and fiscal year accomplishments, ongoing activities, [those begun prior to 2016] and new initiatives [those begun during 2016].

The efforts by the teams within OSA are deeply appreciated. Ms. Taylor Cox developed drafts and coordinated its editing and production. The following list includes the current and former staff, fellows, and contractors who supported OSA in 2016.

Name	Position
Thomas Sinks, Ph.D.	Director
Mary Greene, Ph.D.	Deputy Director
Michael Bender	Program Analyst
Robin Clarke	Program Analyst
Christine Snowden (detail)	Program Analyst
Lu-Ann Kleibacker	Former Program Analyst
Sheryl Mebane	Training Coordinator
Taylor Cox (contractor)	Management Support Associate
Manisha Kumar (contractor)	Science Policy Outreach Support Associate
Reba Brewington	Former SEE/Grantee
Nathan McIntyre (contractor)	Former Management Support Associate
Kristin Cassidy (contractor)	Former Science Policy Outreach Support Associate
Scientific Integrity Program	
Francesca Grifo, Ph.D.	Scientific Integrity Official
Martha Otto	Scientific Integrity Staff Member
Cheryl Hawkins, Ph.D. (detail)	Scientific Integrity Staff Member
Lorna Parkinson (contractor)	Scientific Integrity Research Support Associate
Emily Brantner (contractor)	Scientific Integrity Outreach Support Associate
Melinda Gormley, Ph.D. (fellow)	Former AAAS Fellow
Gary Russo (detail)	Former Scientific Integrity Staff Member
Science and Technology Policy Council	
Anand Mudambi, Ph.D.	STPC Coordinator
Greg Susanke	LEF Coordinator
Tom O'Farrell, Ph.D.	STPC Staff
Megan Christian (contractor)	Former STPC Support Associate
Amanda Redfern (contractor)	Former STPC Support Associate
Program on Human Research Ethics and Oversight	
Toby Schonfeld, Ph.D.	Former Human Subjects Research Review Official
Dan Nelson (ORD Support)	Human Subjects Research Staff Member
Jim Downing	Designated Federal Official for HSRB
Julia Nagy (contractor)	Human Subjects Research Support Associate
Risk Assessment Forum	
Michael Broder, Ph.D.	Exposure Science Coordinator
Julie Fitzpatrick	Human Health Science Coordinator
Lawrence Martin	Ecological Science Coordinator
Beth Brewer (fellow)	Former ORISE Fellow
Forum on Environmental Measurements and Environmental Laboratory Advisory Board	
Lara Phelps	Measurements and Modeling Coordinator
Marie Russell (fellow)	ASPPH Fellow
Tegan Lavoie (fellow)	Former ORISE Fellow

TABLE OF CONTENTS

Letter from Thomas Burke, EPA Science Advisor	i
Office of the Science Advisor in 2016	ii
At A Glance	ii
OSA 2016 Highlights	ii
History of OSA and its Programs	iii
Acknowledgements	iv
The Office of the Science Advisor	1
A. Accomplishments	1
B. Ongoing Activities.....	1
C. New Initiatives.....	1
D. Future Opportunities.....	1
Science and Technology Policy Council (STPC)	2
A. Accomplishments	2
B. Ongoing Activities.....	2
C. New Initiatives.....	2
STPC Standing Groups	3
Forum on Environmental Measurements (FEM)	3
A. Accomplishments	3
B. Ongoing Activities.....	3
C. Future Opportunities.....	4
Laboratory Enterprise Forum (LEF)	5
A. Accomplishments	5
B. New Initiatives	5
C. Future Opportunities	5
Peer Review Advisory Group (PRAG)	6
A. Accomplishments	6
B. Ongoing Activities	6
C. Future Opportunities	6
Risk Assessment Forum (RAF)	7
A. Accomplishments	7
B. Ongoing Activities.....	7
C. New Initiatives.....	8
Programs Within OSA	9
Program in Human Research Ethics and Oversight	9
A. Accomplishments	9
B. Ongoing Activities.....	10
C. New Initiatives.....	10

D. Future Opportunities.....	10
Scientific Integrity	11
Federal Advisory Committees	12
Humand Studies Review Board (HSRB)	12
A. Accomplishments	12
B. Future Opportunities	13
Environmental Laboratory Advisory Board (ELAB)	14
A. Accomplishments	14
B. Ongoing Activities	14
C. New Initiatives	14
Glossary	15
Appendix	17
A. Table of OSA Projects	17
B. FACA Committee Members	19

THE OFFICE OF THE SCIENCE ADVISOR

WHAT IS THE OFFICE OF THE SCIENCE ADVISOR?

The Office of the Science Advisor (OSA) is organizationally located alongside the Immediate Office of the Assistant Administrator for the Office of Research and Development (ORD). This placement assures that the Science Advisor is able to reach across the Agency on science policy issues that involve any program, office or region and also able to dive deeply into the scientific expertise that exists within EPA's ORD.

OSA supports the Science Advisor's role in promoting, harmonizing, and monitoring cross-Agency science policy. OSA staff are located in Washington DC (headquarters) and Research Triangle Park, NC. They support the Agency's Science and Technology Policy Council and its standing groups, the Agency's Scientific Integrity Policy, and the Agency's protection of human subjects in research.

A. ACCOMPLISHMENTS

- OSA released to the public the Agency [*Plan to Increase Access to EPA-funded Research Results*](#).
- OSA completed a plan for support of EPA's regional science and technology work.
- OSA created and implemented a new project database and dashboard to manage its projects. A list of projects maintained in this new database can be found in [Appendix A](#).
- OSA refreshed its performance metrics to better understand the value its work has to the Agency.
- OSA completed and released [EPA's Scientific Collections Policy](#): Improving the Management of and Access to Scientific Collections.

B. ONGOING ACTIVITIES

- OSA coordinated the Agency process and funding for the Presidential Early Career Award for Scientists and Engineers (PECASE), the highest honor given by the U.S. government to outstanding early-career engineers and scientists. The 2013 EPA awardees were Dr. Rebecca Dodder (ORD) and Dr. Alex Marten (OP). OSA forwarded two nominees for the 2014 awards and started the nomination process for the 2015 and 2016 awards.

C. NEW INITIATIVES

- OSA provided operational and management support for the Agency's Strategic Foresight Pilot Project, a joint project between OSA and the Office of the Chief Financial Officer.

D. FUTURE OPPORTUNITIES

- OSA will partner with the Office of Environmental Information (OEI) to establish a cross-Agency forum that implements the *Plan to Increase Access to Results of EPA-Funded Scientific Research* during 2017 and 2018.
- OSA will establish a leadership position to promote and coordinate regional science and technology work.
- OSA will partner with OCFO to implement Strategic Foresight Planning.

SCIENCE AND TECHNOLOGY POLICY COUNCIL (STPC)

WHAT IS THE STPC?

The Science and Technology Policy Council (STPC) was established in 1993 as a cross-Agency decision-making body chaired by the Science Advisor and comprised of senior Agency executives. It works to identify critical science and technology issues and develop and implement policies to help advance the Agency's environmental and public health priorities.

The STPC charters and oversees established councils and fora (e.g., Risk Assessment Forum, Forum on Environmental Measurements, Laboratory Enterprise Forum) as well as ad hoc committees and workgroups to accomplish its initiatives.

A. ACCOMPLISHMENTS

During 2016, the STPC finalized two RAF reports and sent one RAF report for public comment and peer review.

The STPC also finalized the following:

Charters:

- STPC Charter (April 2016) – Full Charter can be found on [OSA's website](#).
- RAF Charter (November 2016) – Full Charter can be found on [OSA's website](#).

Other:

- Two Standard Operating Procedures (SOP) for including *Establishing a STPC Project Charge* and *Product Review, Concurrence, Clearance, Distribution/Dissemination*.

B. ONGOING ACTIVITIES

The existing standing groups under the STPC include the RAF, the FEM, the LEF, and the PRAG. Ongoing projects within each standing group are listed below. Brief descriptions of each project are provided in the standing group sections and [Appendix A](#).

- The Peer Review Advisory Group – 2 ongoing projects
- The Laboratory Enterprise Forum – 2 ongoing projects
- The Risk Assessment Forum – 11 ongoing projects; 5 of these projects are expected to be completed in 2017.
- The Forum on Environmental Measurements – 1 ongoing project

C. NEW INITIATIVES

The STPC approved two new LEF charges and two new RAF charges in 2016.

- Data Collection and Analysis (LEF)
- Laboratory Equipment and Analytical Methods Inventories (LEF)
- White Paper on Explicit Defaults in Reference Value Methodology Development (RAF)
- Cumulative Risk Assessment (RAF)

STPC STANDING GROUPS

FORUM ON ENVIRONMENTAL MEASUREMENTS (FEM)

WHAT IS THE FEM?

The Forum on Environmental Measurements (FEM) was established on April 7, 2003 by the Agency's Science Policy Council (now Science and Technology Policy Council [STPC]) to promote consistency and consensus within EPA on measurement, monitoring, and laboratory science issues.

To fulfill this purpose, the FEM makes recommendations to STPC on basic principles to guide the Agency's measurement community. The FEM also provides EPA and the public with a central point for addressing measurement methodology issues with multi-program impact. FEM members include a representative from each of the Program Offices, Office of Research and Development, and Regional Offices.

A. ACCOMPLISHMENTS

- [MonITOR \(Monitoring Information, Technology, Opportunities & Resources\)](#) was officially launched on the EPA intranet website, creating a sustainable mechanism for EPA programs to share an inventory of routine monitoring programs being used by the Agency (whether the Agency is the primary owner or not) and also an inventory of data gaps and needs across the Agency.
- “The Flexible Approaches to Environmental Measurement – The Evolution of the Performance Approach Annual Report” was produced to highlight each program office participated in an annual report of its progress to continue advancing flexibility in its methods programs. The FEM has concluded that all program offices are continuing to make advancements.
- The FEM issued a letter ensuring the Competency Policies for Acquisition Agreements and Assistance Agreements remain in use until a review of the documents and any necessary modifications can be made. A formal Tribal Consultation was also conducted to ensure participation by the tribal community in the review of the current competency policies.
- Two new initiatives were successfully implemented at NEMC 2016: expansion of the technical program into a half-day on the Friday of the week of the conference; and holding the new technology showcase, which highlights cutting edge technology that is not yet available or has been on the market for less than six months, during the afternoon sessions instead of as an evening event. The 2016 meeting again included over 600 participants.

B. ONGOING ACTIVITIES

- The FEM continues to seek opportunities to improve and ensure flexibility in the Agency's environmental measurements.
- The FEM continues to annually review progress for each program office.
- The FEM connects Agency programs and information across the Agency regarding environmental measurement issues through its Environmental Measurement website,

responds to inquiries, and develops solutions for the challenges presented to our internal and external stakeholders.

- Planning is underway for NEMC 2017 in Washington, DC, on August 7 – 11, 2017.

C. FUTURE OPPORTUNITIES

Although the full scope and specific details are still under discussion, the following activities are being vetted as possible new initiatives. These include:

- Establishment of an intranet site for FEM.
- Transitioning Small Business Innovation Research (SBIR) grant measurement technologies for program office use.
- Developing guidance and policy for method validation for sensors.
- Establishing a validation process for new measurement technology.
- Incorporating the performance approach (i.e., flexibility) into all EPA measurement and method development work.

LABORATORY ENTERPRISE FORUM (LEF)

WHAT IS THE LEF?

The EPA Laboratory Enterprise Forum (LEF) was chartered in July 2015. The impetus for forming the LEF came from a recommendation made by the Synthesis Report of the EPA Laboratory Enterprise Evaluation (March 2015). The Forum promotes effective communication, coordination, and collaboration; develops recommendations for promoting effective and efficient management; and assists in implementing a corporate vision for the Agency's laboratory enterprise.

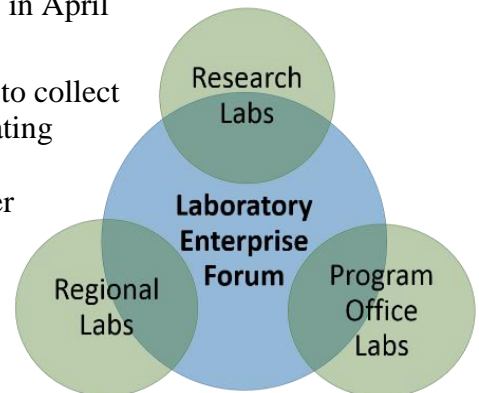
A. ACCOMPLISHMENTS

- OSA developed a vision statement and goals for the entire EPA Laboratory Enterprise.
- LEF members identified 56 challenges for the Forum to address. The LEF sorted these activities into the following categories: workforce, facilities and operations, equipment, and science planning and management.
- LEF developed a diagram to conceptualize the relationships and interactions between EPA's science and technology needs, the EPA Laboratory Enterprise, and the LEF.

B. NEW INITIATIVES

The LEF developed two Charges that were approved by the STPC in April 2016:

- The *Data Collection and Analysis* charge enables the LEF to collect and analyze data about the facilities, work force, and operating costs for the laboratory enterprise, and improve the data collection and reporting process. Using these data and other appropriate metrics and benchmarks, the effort will identify trends and develop recommendations about additional opportunities to improve the Agency's laboratory enterprise.
- The *Laboratory Equipment and Analytical Methods Inventories* workgroup of the LEF began to characterize EPA laboratory equipment and the analytical methods developed to use this equipment. The EPA will also develop mechanisms to promote the use of this information, to efficiently and effectively optimize equipment use, and to assist in characterizing laboratory capabilities.



C. FUTURE OPPORTUNITIES

- There are two additional projects under consideration that include Laboratory Information Technology and Information Management.
- The LEF activities will contribute to OSA's support for Regional Science and Technology efforts.

PEER REVIEW ADVISORY GROUP (PRAG)

WHAT IS THE PRAG?

The Peer Review Advisory Group (PRAG) develops and interprets peer review guidelines, addresses peer review issues, and promotes effective peer review practices across EPA. It also serves as a cross-Agency coordination body to increase the quality and consistency of peer review at EPA.

OSA staff assist the PRAG to:

- Ensure that the Peer Review Handbook is updated to reflect current requirements, policy, oversight, and implementation practices;
- Develop peer review training;
- Provide expert advice to the STPC regarding peer review issues;
- Develop products for internal or external release that advance the use of peer review; and
- Serve as a forum for discussing issues or questions related to peer review.

A. ACCOMPLISHMENTS

- The PRAG completed and released the [EPA Peer Review Handbook, 4th Edition](#), in October 2015 to all Agency employees.
- OSA (with PRAG assistance) conducted webinars and in-person trainings for over 100 people.

B. ONGOING ACTIVITIES

OSA is in the process of developing two peer review related EPA trainings in SkillPort:

- *Peer Review at EPA: Essentials* provides a basic overview of peer review policies and procedures at EPA. It also highlights specific tasks that require decision maker involvement.
- *Peer Review at EPA: Using the Peer Review Handbook* gives a summary of the updates in the [EPA Peer Review Handbook, 4th Edition \(2015\)](#) and a more detailed description of EPA peer review policies and procedures as described in the Handbook.

It is expected that these two trainings will be released for access in SkillPort in early 2017.

C. FUTURE OPPORTUNITIES

- OSA is considering consolidating peer review related activities on the OSA website which will contain all Agency peer review policies and products in addition to any update on PRAG activities.

RISK ASSESSMENT FORUM (RAF)

WHAT IS THE RAF?

The RAF is a standing group under the STPC. The RAF was established in 1993 to harmonize Agency-wide approaches on difficult controversial risk assessment issues. The RAF assembles Agency risk assessment experts to develop risk assessment related products. Products include guidelines, technical panel reports, consultations, and peer review workshops addressing controversial risk assessment topics.

A. ACCOMPLISHMENTS

Below are some of the accomplishments from 2016:

- The RAF finalized [a new RAF Charter](#) – The Charter revisions require STPC approval of RAF projects and working group charges, modifies the role of RAF Oversight Committees, streamlines the RAF review and approval process, and strives for, but does not require, consensus by the RAF members on its products.
- The RAF released for public comment and peer review updated *Guidelines for Human Exposure Assessment*
- The RAF finalized and released the [Generic Ecological Assessment Endpoints \(GEAE\) 2nd Edition, and the Technical Background Paper](#)
- The RAF released final *Weight-of-Evidence in Ecological Risk Assessment*

B. ONGOING ACTIVITIES

The following is a list of ongoing projects and activities in various stages of development within the RAF:

- The *Additivity Report on Cumulative Risk Assessment (CRA)* is a report on the use of dose addition (DA) as one of several discrete aspects of CRA. The product's initial product review has been completed.
- The *Dose-Response Assessment State of the Science Review* is working to develop a State of the Science Review of the critical topic in dose response assessment of methods/approaches and data for quantitatively estimating variability in human physiological responses from exposure to chemicals. The RAF review of this product has been completed.
- Finalize the *Guidelines for Human Exposure Assessment* and provide the EPA assessors with guidance on how to perform exposure assessments. The external review/comment for this product has been completed. A response to comments and finalization of this report is expected in the next year.
- The *Uncertainty and Variability Assessment Action Plan* provides a path forward for EPA to characterize uncertainty and variability in its assessments. The initial draft product has been completed.
- The *Uncertainty and Variability Assessment Current Practices Report and Resource Inventory* inventories available tools, methods, guidance and training across EPA to characterize uncertainty and variability. The initial draft product has been completed.

C. NEW INITIATIVES

The STPC approved two new charges for the RAF during 2016:

- A charge to “Develop a White Paper on Explicit Defaults in Reference Value Methodology.” The white paper will evaluate the available information relevant to two areas of uncertainty considered in the derivation of reference values: the database and sub chronic-to-chronic-duration uncertainty factors
- A charge to create *Cumulative Risk Assessment Guidelines* that will provide standard methods for planning and scoping cumulative risk assessments at EPA

PROGRAMS WITHIN OSA

PROGRAM IN HUMAN RESEARCH ETHICS AND OVERSIGHT

WHAT IS THE PHREO?

OSA's Program in Human Research Ethics and Oversight (PHREO) supports the ethical conduct and regulatory compliance of human subjects research (HSR) conducted or supported by the EPA with the Federal Policy for Protection of Subjects. This support is accomplished through project review, cross-Agency partnership, and education and training.

The PHREO reviews, supports, and guides the work of EPA affiliated or supported researchers involved in human subjects research to ensure that the rights and welfare of human research subjects are protected. All research involving human subjects proposed by EPA staff or EPA supported researchers must be approved by the EPA Human Subjects Research Review Official (HSRRO) before HSR may begin.

A. ACCOMPLISHMENTS

- The Human Subjects Research Application Portal (HSRAP) system for electronic submissions was developed and came online.
- During FY2016, 93 research projects were reviewed. Of these, 61 were approved, 6 were determined exempt, 26 did not require further review. Of the 93 submissions, 84% were extramural and 16% were intramural. Seventy-six percent of these submissions came from the National Center for Environmental Research (NCER), 12% from the National Health and Environmental Effects Research Lab (NHEERL), 9% from other groups within ORD, and 3% from EPA regions.
- The PHREO and the EPA Office of General Counsel revised an illogical interpretation of intentional [reduced] exposure research of study subjects.
- The PHREO updated EPA's *Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research* ([Order 1000.17A dated 2016](#)). These updates ensure that EPA is consistent with contemporary research practice and streamline HSRRO approval of extramural research plans.
- The PHREO created three training initiatives that increase the sensitivity to, and awareness of, Human Subjects Research (HSR) issues across the Agency and equip project managers, investigators, and others with the tools necessary to meet HSR requirements at EPA. Initiatives included:
 - Human Research Ethics Council (HREC) members completed online Collaborative Institutional Training Initiative (CITI) training as well as interactive quarterly training activities throughout the past year.
 - PHREO conducted a yearlong HSR training program for staff in NCER. Twenty-seven NCER personnel "graduated" from this pilot training program that combined online CITI training modules with topic-specific training sessions to reinforce HSR concepts specific to the EPA.
 - HSRRO delivered multiple webinars and in-person seminars to groups across the Agency, on request.

B. ONGOING ACTIVITIES

- Every HSR project proposed to be conducted or funded by EPA is routed for HSRRO review through the Human Subjects Research Application Portal (HSRAP).
- PHREO has contracted the National Academy of Sciences (NAS) to conduct a report regarding EPA human exposure studies. The final report is expected in 2017.
- PHREO training initiatives continue on general and specific topics, to promote highest standards in the conduct of Agency research.
- PHREO participates on an InterAgency Workgroup, coordinated by the White House, to revise the Common Rule regulations that govern HSR. A revised rule may be released before the end of 2016.

C. NEW INITIATIVES

During 2016, PHREO undertook two new initiatives including:

- Developing an EPA Human Subjects Research Resource Book, incorporating government-wide and EPA-specific guidance. This resource book will provide an introduction and overview of HSR at the EPA to investigators and EPA personnel.
- Developing a PHREO Standard Operating Procedures (SOP) Manual. This manual will guide EPA employees through the regulatory and ethical requirements for conducting HSR. The SOP manual will be used as a toolbox by researchers, Project Officers (PO), research coordinators, and any other persons involved in HSR at EPA. The SOP Manual should be online in early 2017.

D. FUTURE OPPORTUNITIES

The PHREO will continue working to:

- Fill the current vacancy in the HSRRO position with a qualified leader.
- Should a Final Revised Common Rule be released by HHS, update EPA regulations, as necessary, to reflect changes, and to harmonize with the current standards.
- Work with EPA's Office of Grants and Debarment to implement language changes to the grant Funding Recommendation in Integrated Grants Management System (IGMS), reflecting recent revisions to Policy Order 1000.17A.
- Proceed with phase II development of the HSRAP system, to provide access to all required personnel in the research approval chain (including Branch Chiefs, Division Directors, etc.).

SCIENTIFIC INTEGRITY

The Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity of the science on which it relies. EPA's Scientific Integrity Policy was issued in February 2012 and provides a framework to promote the science on which it relies. The Policy applies to all EPA employees including scientists, managers, and political appointees as well as contractors, grantees, collaborators, and volunteers. The policy provides a framework that promotes scientific and ethical standards, including quality standards, communications with the public, use of peer review and advisory committees, and professional development.

The EPA Scientific Integrity Official is located within OSA. The Official is supported by a team of OSA staff and contractors. A 2016 Annual Scientific Integrity Report is required to be released within EPA under the policy and will provide a companion to the OSA 2016 Annual Report. Two significant scientific integrity accomplishments are reported here:

- In 2016, the Scientific Integrity team developed four, and released two, video trainings for EPA staff. These "white board" video trainings were released to the agency through its Scientific Integrity Committee. During 2016, more than 7000 EPA staff have received the trainings. The video training received a Telly Award.
- In 2016, the Scientific Integrity team released [Best Practices for Designating Authorship](#). The best practices described in the document apply to any EPA work product where authorship is designated, including but not limited to journal articles, reports, presentations, posters, documentation of models or software, communications products, technical support documents, and guidance documents. The document encourages early and frequent discussions among collaborators and awareness of common authorship abuses.

See website for full 2016 Annual Report.

FEDERAL ADVISORY COMMITTEES

HUMAN STUDIES REVIEW BOARD (HSRB)

WHAT IS THE HSRB?

The Human Studies Review Board (HSRB) is a federal advisory committee created to review and comment on proposed and completed third-party pesticide or antimicrobial research involving intentional human subject exposure, when the results are to be submitted or relied upon in connection with an action that EPA administers, including the pesticide laws.

A. ACCOMPLISHMENTS

During 2016, the HSRB provided advice and recommendations to EPA's Office of Pesticide Programs on the following human subjects research studies:

- **Completed Study from the U.S. Department of Agriculture Describing Laboratory Evaluation of Bite Protection from Repellent-Impregnated Clothing for the United States Military**
 - Study submitted by USDA
 - The Board concluded that the research is sufficient for evaluation of etofenprox-treated military clothing.
- **Protocol for Testing of S.C. Johnson Personal Tick Repellent Products to Support Use of EPA Repellency Awareness Graphic**
 - Study submitted by S.C. Johnson
 - The Board concluded that the protocol, if modified, is likely to generate scientifically reliable data, useful for estimating the complete protection time of various EPA-registered S.C. Johnson skin-applied repellents.
- **A published study entitled Assessing Intermittent Pesticide Exposure from Flea Control Collars Containing the Organophosphorus Insecticide Tetrachlorvinphos (TCVP)**

M. Keith Davis, J. Scott Boone, John E. Moran, John W. Tyler and Janice E. Chambers. Journal of Exposure Science and Environmental Epidemiology (2008) 18, 564–570

 - Study obtained by OPP
 - The Board found the research scientifically sound for evaluating potential exposures of adults and children from having contact with dogs treated with tetrachlorvinphos containing pet collars.
- **Field Testing of five SC Johnson Personal Mosquito Repellent Products to Support their Use of the EPA Repellency Awareness Graphic.**
 - Studies submitted by S.C. Johnson *Test Substances:*
MARK-3 OFF! Deep Woods Sportsmen Insect Repellent I (Maximum Strength Pump Spray Deep Woods OFF! EPA Reg. No. 4822-276)

MARK-8 OFF! Deep Woods Insect Repellent V (OFF! Insect Repellent Formula, EPA Reg. No. 4822-167)

MARK-2 OFF! Deep Woods Sportsmen Insect Repellent II (UNSCENTED DEEP WOODS OFF! EPA Reg. No. 4822-397)

MARK-4 OFF! Active Insect Repellent I (Unscented OFF! Insect Repellent, EPA Reg. No. 4822-380)

MARK-5 OFF! Family Care Insect Repellent IV (Unscented) (UNSCENTED OFF! SKINTASTIC SPRAY INSECT REPELLENT, EPA Reg. No. 4822-395)

- The HSRB found the studies useful for estimating protection time against mosquitoes. Available information indicates the research was conducted in substantial compliance with applicable provisions of 40 CFR part 26 subparts K and L.
- **Completed Study and Monograph Report for Agricultural Handler Exposure for Wettable Powders (AHE80 and AHE1015).**
 - Research submitted by the Agricultural Handler Exposure Task Force (AHETF).
 - The reported research was faithful to the protocol and generated reliable data, subject to some limitations identified by the HSRB. Studies were conducted in substantial compliance with 40 CFR 26 subparts K and L.
- **Completed Study and Monograph Report for Agricultural Handler Exposure during Mixing/Loading of Pesticide Products in Water Soluble Packets (AHE 120 and AHE 1014).**
 - Research submitted by the Agricultural Handler Exposure Task Force (AHETF).
 - The reported research was faithful to the design and protocol and generated reliable data, subject to some limitations by the HSRB.

B. FUTURE OPPORTUNITIES

The HSRB will continue to review research protocols and studies of intentional human exposures to pesticides and antimicrobial products. The HSRB is expected to be relocated to the Office of Science Coordination and Policy within the Office of Chemical Safety and Pollution Prevention in 2017.

ENVIRONMENTAL LABORATORY ADVISORY BOARD (ELAB)

WHAT IS ELAB?

Established in 1995, the Environmental Laboratory Advisory Board (ELAB) provides EPA consensus advice, information and recommendations on enhancing EPA's measurement programs and facilitating the operation and expansion of a national environmental accreditation program. ELAB consists of [16 members](#) who meet monthly.

A. ACCOMPLISHMENTS

ELAB issued three consensus recommendations in 2016:

- Reporting of Compliance Data with Qualifiers that Do Not Impact Data Usability
- Method Harmonization Update and Method Comparisons
- Laboratory Involvement in the Quality Assurance Project Plan Development Process

B. ONGOING ACTIVITIES

The possibilities for discussion and recommendation by ELAB are only limited to what fits within the scope of its charter. The Board is always open to exploring additional areas needing attention.

C. NEW INITIATIVES

There are five topic areas the Board is vetting to determine how it will proceed in advising the Agency:

- In-line and On-line Monitoring
- Selected Ion Monitoring (SIM)
- Whole Effluent Toxicology (WET)
- Cyanide
- GC/MS Spectral Libraries

GLOSSARY

CITI – Collaborative Institutional Training Initiative

CRA – Cumulative Risk Assessment

DA – Dose Addition

ELAB – Environmental Laboratory Advisory Board

EPA – Environmental Protection Agency

FACA – Federal Advisory Committee

FAQ – Frequently Asked Question

FEM – Forum on Environmental Measurements

HREC – Human Research Ethics Council

HSR – Human Subjects Research

HSRAP – Human Subjects Research Application Portal

HSRB – Human Studies Review Board

HSRRO – Human Subjects Research Review Official

IGMS – Integrated Grants Management System

IT/IM – Information Technology/Information Management

LEF – Laboratory Enterprise Forum

MonITOR – Monitoring Information, Technology, Opportunities & Resources

NAS – National Academy of Sciences

NCER – National Center for Environmental Research

NEMC – National Environmental Monitoring Conference

NHEERL – National Health and Environmental Effects Research Lab

OGC – Office of General Counsel

OMB – Office of Management and Budget

ORD – Office of Research and Development

OSA – Office of the Science Advisor

PECASE – Presidential Early Career Award for Scientists and Engineers

PHREO – Program in Human Research Ethics and Oversight

PO – Project Officer

PRAG – Peer Review Advisory Group

RAF – Risk Assessment Forum

RTP – Research Triangle Park, North Carolina

SA – Science Advisor

SBIR – Small Business Innovation Research

ScI – Scientific Integrity

SOP – Standard Operating Procedure

STPC – Science and Technology Policy Council

U&V – Uncertainty & Variability

USDA – United States Department of Agriculture

APPENDIX

A. TABLE OF OSA PROJECTS

Name of Project	Standing Group	Start Date	Last Milestone Completed
Public Access Plan	STPC ¹	2/22/2013	Final Concurrence/Approval
MonITOR	FEM ²	1/1/2013	Product Release
Data Collection and Analysis: Laboratory Enterprise Data	LEF ³	4/1/2016	Workgroup/Panel Formed
Laboratory Equipment and Analytical Methods	LEF	4/1/2016	Workgroup/Panel Formed
Peer Review Essential Concepts for Managers Training Module	PRAG ⁴	11/1/2015	Initial Product Review Completed
Peer Review Handbook	PRAG	8/1/2012	Product Released
Using EPA's New Peer Review Handbook Training Module	PRAG	12/1/2015	Initial Draft Product Completed
Additivity Report on CRA	RAF ⁵	5/1/2011	Initial Product Review Completed
CRA at EPA Report	RAF	2/1/2014	Initial Product Review Completed
CRA Literature Review	RAF	1/1/2013	Initial Product Review Completed
Cumulative Risk Assessment Guidelines	RAF	2/1/2000	Initial Draft Product Completed
Dose-Response Assessment Case Study Scoping Document	RAF	4/20/2015	Initial Draft Product Completed
Dose-Response Assessment Plan	RAF	6/1/2016	Initial Draft Product Completed
Dose-Response Assessment State of the Science Review	RAF	4/20/2015	Initial Product Review Completed
Explicit Defaults in Reference Value Methodology	RAF	3/18/2016	Project Initiated
Generic Ecological Assessment Endpoints, Second Edition	RAF	1/1/2013	Product Released
Guidelines for Human Exposure Assessment	RAF	10/12/2004	External Review/Comment Completed
Uncertainty and Variability Assessment Action Plan	RAF	5/1/2014	Initial Draft Product Complete

¹ Science and Technology Policy Council

² Forum on Environmental Measurements

³ Laboratory Enterprise Forum

⁴ Peer Review Advisory Group

⁵ Risk Assessment Forum

Uncertainty and Variability Assessment Current Practices Report and Resource Inventory	RAF	3/1/2013	Initial Draft Product Complete
Weight of Evidence in Ecological Risk Assessment	RAF	8/6/2014	Product Approved for External Review/Comment
Common Rule Revision Workgroup	HSR ⁶	9/8/2015	
EPA Order 1000.17A Revisions	HSR	6/8/2015	Product Released
HSR at EPA FAQ Communications Document	HSR	6/2/2015	Product Released
HSR Resource Book	HSR	10/13/2015	Product Approved for External Review/Comment
HSR SOP Manual	HSR	8/4/2015	Released into External Review/Comment
HSR Training Initiatives	HSR	4/1/2015	Product Released
NAS Task Order on Risk in Controlled Exposure Studies	HSR	9/15/2014	Workgroup/Panel Formed
2016 Annual Progress Assessment and Reporting	Sci ⁷	9/20/2016	Project Initiated
Authorship Best Practices	Sci	8/1/2014	Product Released
Best Practices for Designating Authorship	Sci	8/1/2014	Product Released
Clearance Procedures	Sci	1/1/2015	Initial Product Review Completed
Intranet Scientific Integrity Page	Sci	3/1/2015	Product Released
Internet Scientific Integrity Page	Sci	10/1/2014	Product Released
Language for Grants and Contracts	Sci	5/12/2015	Response to External Review Completed
Management Outreach and Training	Sci	12/1/2015	Project Initiated
Scientific Integrity Training Evaluation	Sci	9/20/2016	Project Initiated
Scientific Integrity Training Implementation	Sci	4/1/2016	Product Approved for External Review
Scientific Integrity Survey	Sci	6/1/2015	Workgroup/Panel Formed

⁶ Human Subjects Research

⁷ Scientific Integrity

B. FACA COMMITTEE MEMBERS

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Kendra L. Lawrence, Ph.D., BCE, PMP	Consultant to the Board

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Ms. Sharon Mertens	The NELAC Institute
Ms. Lara P. Phelps, DFO	U.S. EPA
Dr. Mahesh P. Pujari	National Association of Clean Water Agencies
Mr. Elan Rieser	Utility Water Act Group
Ms. Debra A. Waller	State of New Jersey Department of Health