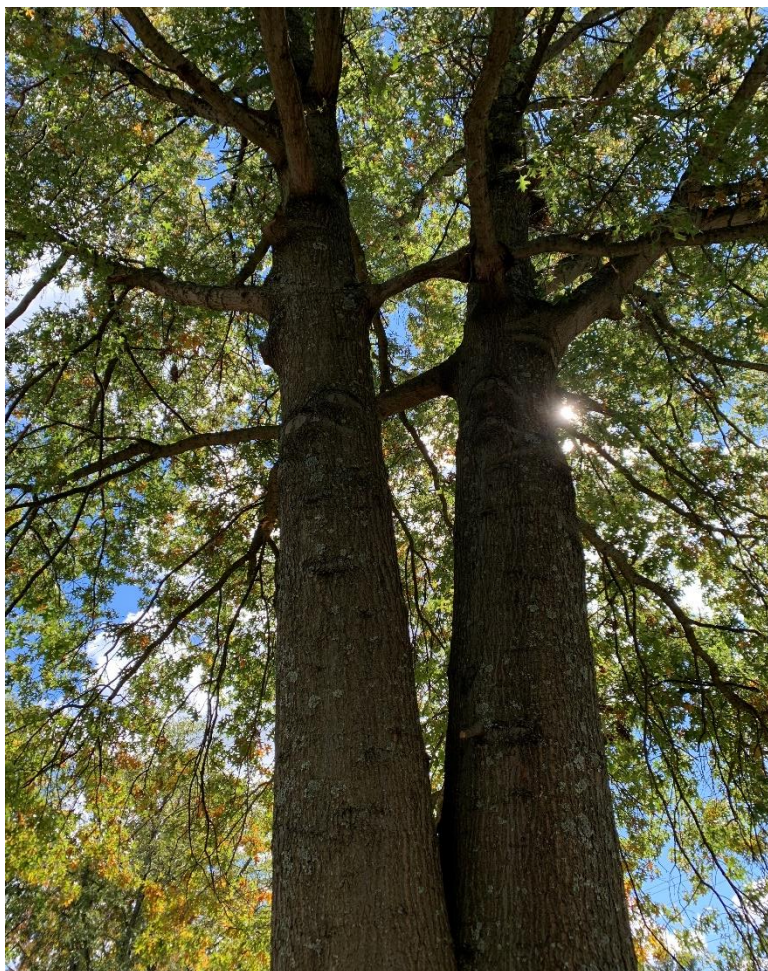




# TERA

TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT



## ANNUAL REPORT 2020

INDEPENDENT • NON-PROFIT • SCIENCE  
*protecting public health*

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## BOARD OF DIRECTORS

Board Chairperson  
Finance Committee Chair  
Gregery S. Romshe, CMA  
The Procter & Gamble Company

Audit Committee Chair  
Chase D. Wright  
Deloitte

TERA President  
Patricia McGinnis Ph.D., DABT  
Toxicology Excellence for Risk  
Assessment (TERA)

# ABOUT US



Toxicology Excellence for Risk Assessment (TERA) is a 501(c)(3) non-profit corporation dedicated to the best use of toxicity data for risk assessment.

TERA was organized as a non-profit corporation to facilitate successful partnerships between environmental, industry and government groups. Through these partnerships, TERA helps environmental, industry, and government groups find common ground through the application of robust and cutting-edge science to risk assessment. Improvements in the science and practice of risk assessment are developed.

# MISSION

## TERA's Mission

Independence from all parties and groups is essential for our science and results to be credible by all parties.

TERA has instituted policies and procedures and maintains a corporate environment that ensures that all our work efforts are conducted in a manner that maintains our independence.

We perform all our work in a scientifically objective fashion with our results reflecting our best critical analysis and objective evaluation of the scientific information. We are continuously vigilant to make sure that we remain open to new ideas, but we are not swayed or influenced by our funding sponsors, or any other party, in reaching our conclusions or communicating our results.

# CORE PRINCIPLES AND VALUES

## TERA Core Principles and Values

### **Honesty and Integrity**

We operate at the highest level of ethical and scientific standards, fully communicating issues and uncertainties.

### **Independence**

We approach our work with an open mind and objectivity, without regard to sponsor or stakeholder interests.

### **Transparency**

We share our work broadly to maximize benefit to public health.

### **Collaboration**

We use collaboration as a fundamental and preferred approach to technical problem resolution.

These core principles guide day-to-day TERA operations from consideration of new projects and sponsors, to our scientific evaluations and communication of results. Numerous measures ensure our work is based upon our principles.



## TERA Core Principles and Values

We recognize the importance of independence and scientific objectivity and continually monitor projects and personal work efforts to ensure we maintain our high ethical and scientific standards.

- We are transparent about how we do our work and the methods and approaches we use, so that others can evaluate and judge the strength and scientific validity of our conclusions.
- We strive to fully characterize and communicate scientific uncertainties and limitations in our work.
- We are transparent about who our funders are and what role they had, if any, in commenting on the TERA scientific opinions or results. We make it clear to all funders and sponsors of our work that TERA is an independent scientific organization and as such we will provide them our independent scientific evaluation and conclusions. We discuss (prior to starting work) the level and types of involvement of the sponsors and other outside parties.
- We offer our independent scientific services to a broad range of sponsors, including government agencies, industry, non-governmental organizations, and consultants. By collaborating with many types of organizations, TERA gains an appreciation and understanding of the scientific perspectives of these various parties. We utilize this understanding and the resulting relationships to identify and encourage collaboration among a range of parties to improve risk assessment and protection of public health.
- We seek to have a balance of work among public and private sector. In recent years, about 2/3 of our work has been for training, non-profit companies, Internal Research and Development (IR&D) and government agencies, and the other 1/3 for industry. See: <http://www.tera.org/about/FundingSources.html> for a breakdown by year.
- TERA evaluates each new project to ensure that it is mission-related, will benefit public health, and that TERA's participation does not pose a conflict of interest, and will make a quality contribution to the effort. We decline projects that do not meet these criteria.
- We strive to publish our work in the peer-reviewed literature or on our website to make the work available to a broad audience.







# TERA

In addition to paid work, TERA provides *pro bono* support to local and state governments, non-government organizations, and others to provide training and to help them address important human health and risk issues.

# A YEAR LIKE NO OTHER

*Distance has never kept us from working with the best and brightest!*

Working from Home	Video Conferencing	Social Distancing	IT Support
			
<p>A long-time TERA tradition.</p> <p>TERA has always employed remote associates in the United States, Canada, and around the globe.</p> <p>TERA also realizes flex time helps employees reduce stress, balance work and personal life, and has always encouraged staff to work from home during inclement weather.</p>	<p>TERA's had video chat in its toolbox for years!</p> <p>While primarily used for staff and project meetings, we have also utilized several types of video chat programs for connecting with clients and collaborators.</p> <p>Through the years, TERA has presented several webinars and trainings using this technology.</p>	<p>Another TERA standard.</p> <p>We had already mastered the art of staying in touch across the miles by using instant messaging, webinars, and video conferencing.</p> <p>For decades TERA has enjoyed its own unique style of multi-email chat with all employees joining in. Just like being in the office!</p>	<p>Everyone else learned in 2020 what TERA has known all along!</p> <p>Having a strong IT department has always been a top TERA priority, to make sure our systems are secure, safe, up-to-date, and in-line with the current US and international government regulations. Our systems meet or exceed DOD &amp; HIPPA requirements.</p>

# THINGS WE MISSED IN 2020

Dose-Response Assessment Boot Camp Fall Course

The Society of Toxicology's (SOT) 58<sup>th</sup> Annual Meeting

TERA's SOT Ice Cream Social

TERA Participation in local Earth Day Activities

Society for Risk Analysis (SRA) Annual Meeting

In Person Meetings

TERA Employee Luncheons!

*We are looking forward to 2021!*

# TERA STATE OF THE SCIENCE 2020

The year 2020 was a good rebuilding year for TERA science. We had a variety of projects from a diverse group of sponsors. We won paper of the year award from the Society of Toxicology's Regulatory and Safety Evaluation Specialty Section for a paper published in 2019. We assisted developed numerous reports, multiple legal cases, conducted **two** scientific meetings, made **seven** presentations, and published **four** papers.

Specific examples of this work include the following:

- Award for Paper of the Year: Michael L. Dourson, Bernard Gadagbui, Chijioke Onyema, Patricia M. McGinnis, Raymond G. York. 2019. Data-derived extrapolation factors for developmental toxicity: A preliminary research case study with perfluorooctanoate (PFOA). Regulatory Toxicology and Pharmacology. 108: 104446.
- Four legal cases/opinions covering chemical exposures and environmental contamination issues.
- Several scientific reports including:
  - An Evergreen Commentary on the Background Sources of Ethylene Oxide
  - Development of Chemical Specific Adjustment Factor (CSAF) for Procymidone (PCM) Report.
  - Review of reports for nonprofit scientific organization
- Several scientific meetings including:
  - WEEL Committee meeting (October 2020)
  - Beyond Science and Decisions: From Problem Formulation to Risk Assessment, Workshop XI at the Cincinnati offices of the National Institute for Occupational Safety and Health
- Presentations including:
  - Chemical-specific Adjustment Factor (CSAF) for Developmental Toxicity of Perfluorooctanoate (PFOA) and Chemical-Specific Adjustment Factor (CSAF) for Procymidone (PCM). 2020 SRA Annual Meeting, December 14, 2020.

- "Overview of Risk Assessment", "Cancer and Noncancer Dose Response Assessments, and "Risk Characterization" at the Society of Toxicology-sponsored International Workshop on Human Health Risk Assessment. Chitkara University, Himachal Pradesh, India. September 17, 2020.
- "Science Policy Issues: TSCA Reform – Four Years Later" ELI, Bergeson & Campbell, and the George Washington University Milken Institute School of Public Health Co-Sponsored Conference with the Environmental Law Institute. June 24, 2020.
- "Risk Assessment Perspectives" Current skin safety assessment advances and challenges. A Safer-World-By-Design panel webinar and interaction meeting. April 7, 2020.
- WHO Chemical Risk Assessment Network Training Webinar: Training Courses on Adverse Outcome Pathways, Dose-Response Assessment and Chemicals Management. April 6, 2020.
- "Food Safety Regulations: Carcinogens and the Relevance of the Delaney Clause: A Pro Delaney Perspective" American Association for the Advancement of Science. Seattle, WA. February 16, 2020.
- "Update: Whither the safe dose for perfluorooctanonate (PFOA)?" Toxicology Forum, Tysons, Virginia, January 28. 2020.
- Published papers including:
  - Michael Dourson, Bernard Gadagbui; Chijoke Onyema; Patricia M McGinnis 2020. A Commentary on Some Epidemiology Data for Chlorpyrifos. Regulatory Toxicology and Pharmacology. Volume 113, June 2020, 104616.
  - Danzeisen R, D L Williams, V Viegas, M Dourson, S Verberckmoes, A Burzlaff. 2020. Bioelution, Bioavailability, and Toxicity of Cobalt Compounds Correlate. Toxicological Sciences. DOI [10.1093/toxsci/kfz249](https://doi.org/10.1093/toxsci/kfz249)
  - Mikkonen, Antti T., Jennifer Martin, Michael L. Dourson, Andrea Hinwood, Mark S. Johnson. 2020. Suggestions for Improving the Characterisation of Risk from Exposures to Per and Polyfluorinated Alkyl Substances (PFAS). Environ Toxicol Chem 2021;00:1–16. <https://doi.org/10.1002/etc.4931>.
  - Bernard Gadagbui, Justin Moore, Ann Parker, David McCready, Andrew D Monnot, Lindsey Garnick, Melissa Vincent, Pamela Spencer, Andrew Maier. 2020. Derivation of cancer no significant risk levels and screening safety assessment for 2-nitropropane in spray products. J Appl Toxicol. 40(5):691-705. doi: 10.1002/jat.3937. Epub 2020 Feb 6.

# VISITING SCIENTISTS AND FELLOWS PROGRAMS

TERA has developed both the Visiting Scientist and Fellow Programs to encourage collaboration with others and to improve risk assessment practices.

**Visiting Scientists** are those engaged with TERA for a fixed period of time or on a defined project. Project work may or may not be onsite at TERA's Cincinnati office. While visiting scientists are often senior scientists, positions can also be considered for scientists who are beyond internship level, but for whom a period at TERA would be of mutual benefit.

**TERA Fellows** are senior scientists associated with TERA on a longer-term basis with ongoing scientific interactions.

Fellows and Visiting Scientists are not employees of TERA, but rather scientists who share TERA's mission and values and seek to improve the practice of risk assessment. TERA collaborates with Visiting Scientists and/or TERA Fellows on projects of mutual interest.

In the past, scientists have worked with TERA and coauthored manuscripts or reports on a variety of topics, including methods for evaluating persistent and bioaccumulative chemicals, exposure assessment methods, dose-response modeling, mixtures assessment, and investigating the magnitude of adult-to-child toxicokinetic differences in inhalation dosimetry of gases.

# AWARDS AND HONORS

Women in Toxicology (WIT) asked Dr. Bernard Gadagbui to serve on a subcommittee to support the WIT Awards Nomination Committee for the SOT National Awards. WIT promotes the recruitment and retention of women to a profession in the toxicological sciences. WIT is a Special Interest group of the Society of Toxicology (SOT)

Award for Paper of the Year: Michael L. Dourson, Bernard Gadagbui, Chijioke Onyema, Patricia M. McGinnis, Raymond G. York. 2019. Data derived Extrapolation Factors for developmental toxicity: A preliminary research case study with perfluorooctanoate (PFOA). Regulatory Toxicology and Pharmacology. 108: 104446.

Toxicology Excellence for Risk Assessment (TERA) has earned, and maintains the Independent Charities Seal of Excellence.

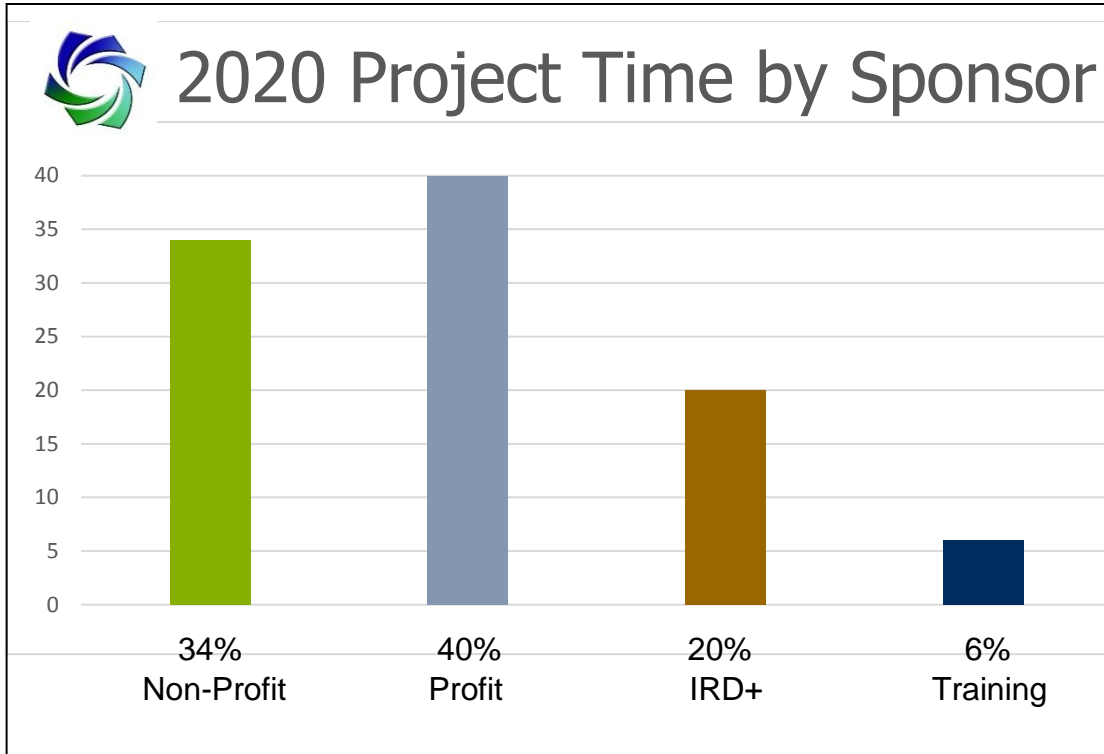


This award is given to the members of Independent Charities of America and Local Independent Charities of America that have, upon rigorous independent review, been able to certify, document, and demonstrate on an annual basis that they meet the highest standards of public accountability, program effectiveness, and cost effectiveness.

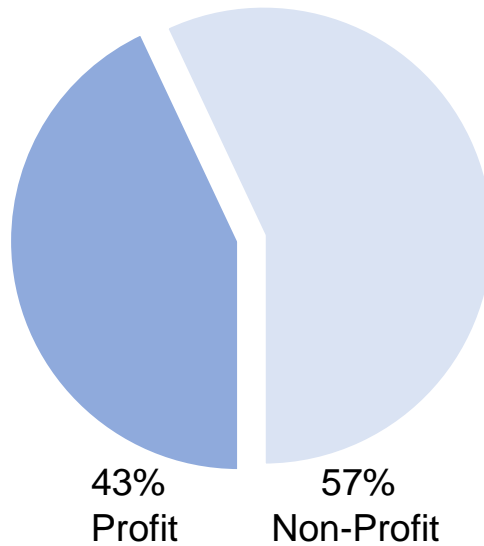
These standards include those required by the US Government for inclusion in the Combined Federal Campaign, probably the most exclusive fund drive in the world. Of the 1,000,000 charities operating in the United States today, it is estimated that fewer than 50,000, or 5 percent, meet or exceed these standards, and, of those, fewer than 2,000 have been awarded this seal.



# THE NUMBERS



All Time by Sponsor: Profit vs. Non-Profit





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