SOT | Society of Toxicology

2022 Global Senior Scholar Exchange Program Host

HOST APPLICANT
NAME (FIRST, MIDDLE INITIAL, LAST): BERNARD GADAGBUI
TITLE: SENIOR TOXICOLOGIST AND DIRECTOR OF TRAINING
Institution: Toxicology Excellence for Risk Assessment (TERA)

ADDITIONAL HOST APPLICANT (IF APPLICABLE)
NAME (FIRST, MIDDLE INITIAL, LAST): MICHAEL L. DOURSON
TITLE: PRESIDENT OF TERA
Institution: Toxicology Excellence for Risk Assessment (TERA)

ORGANIZATIONAL OVERVIEW:
- Department Chair
- Number of Faculty/Staff and Disciplines Represented

Toxicology Excellence for Risk Assessment (TERA) is an independent, non-profit, 501(c)(3) corporation organized in 1995 for innovative scientific and educational purposes. TERA's mission is to support public health protection through the best use of toxicity and exposure information in the development of human health risk assessments. We accomplish this mission by developing risk values, communicating risk assessment information, organizing expert reviews and workshops, improving risk methods through research, and educating risk managers, assessors, and the public on risk assessment issues. TERA has extensive corporate experience in developing and applying risk assessment guidance and methods; developing cross-jurisdictional methods reviews; developing hazard and risk prioritization frameworks; analyzing toxicity and epidemiology data for single chemical and mixtures toxicological assessments; and developing methods and assessments for human health and chemical risk assessment for environmental, pharmaceuticals, consumer products, and occupational exposure scenarios. Our assessment program utilizes state-of-the-science risk methods (some having been developed by our scientific staff) and guidance used by the leading government agencies and other authoritative bodies.

TERA's main office is in Cincinnati, Ohio, plus several staff members work from satellite offices. TERA employees including highly trained generalists and specialists and is led by our President, Dr. Michael Dourson, DABT, FATS, FSRA, with Dr. Bernard Gadagbui, DABT, ERT, as the Director of Training. Individual TERA scientists have training in toxicology, chemistry, biochemistry, molecular biology, industrial hygiene, pharmacology, epidemiology, biomathematics, environmental science, biomedical science, aquatic toxicology, education, and technical and scientific communication. Many of our senior staff are recognized leaders in the toxicology, occupational toxicology, industrial hygiene, and risk assessment fields. The majority of TERA's staff members hold a PhD or Masters; many are Diplomates of the American Board of Toxicology (DABT) and one is also included in the UK Register of Toxicologists.

We would be pleased to host a global scholar at our Cincinnati office where we have a private office and desk available for visiting scientist's use.

APPLICANT'S STATEMENT OF IMPACT: (250-500 words)
What attributes, skills and experiences do you plan to offer to a visiting Scholar to enable them to enhance their toxicology capabilities within their program, research and within their developing region? Specifically, discuss where your focus would be during the year of the exchange compared to the next 2-5 years of your Host-Scholar relationship.

The goal of TERA is to increase our reach and capabilities in developing and providing risk training programs that meet the specific needs of different countries and regions. Our scientists are leaders in human health and ecological and occupational risk assessment and have extensive experience in developing and conducting training of scientists and regulators in risk assessment and toxicology and risk assessment techniques. One of our organization's mid-range goals is to bring our risk assessment training to more countries outside of Europe and North America. Hosting a scholar from a developing country would provide us with the opportunity to learn directly from an experienced educator and risk practitioner how we can best design and deliver risk training and better align our training with the needs of the students and their countries and cultures. It will also provide the opportunity for us to better understand issues in integrating human and ecological risk problem formulation and assessment, which we can then incorporate into many of our projects and work. In addition, we would establish an on-going relationship with the scholar and the institution that would allow us to collaborate on future initiatives, including developing targeted training for regulators and other interested scientists in the developing countries.

While at TERA, we would learn from the Scholar about the specific situations with environmental and occupational chemicals in their home country and the risk assessment and toxicology tools and techniques that are used there. We would share our knowledge in toxicology and human health risk assessment methods and techniques and introduce the Scholar to several leading toxicology and risk assessment scientists in industry, academia, and governmental organizations. The scholar will attend our signature "Dose-Response Assessment Boot Camp", a unique 5-day intensive hands-on training in hazard characterization and dose-response assessment for individuals in the risk assessment or toxicology field. TERA expects to use the visit to the scholar's institution to begin effective education and training of scientists and regulators in risk assessment and toxicology through our Boot Camp.

Within a year, we anticipate collaborating with the scholar to develop effective training modules for students that integrate knowledge of toxicology testing and risk assessment methods and approaches that can be used to evaluate risk and benefits of the use of environmental and occupational chemicals. This training will provide an understanding of the basic concepts of human health, ecological and occupational risk assessment and how these can be used to assess risk to humans and ecological receptors in settings that are unique or relevant to their country. The scholar would also develop country-specific approaches that factor in the uniqueness of the geopolitical divides and will help in mitigating the public health crises in the home country.

In the next 2-5 years, TERA would provide collaborative opportunities that would result in high quality research and academic program development, including joint publications, student exchanges, organizations of meetings and workshops, and in increasing involvement of toxicologists from the scholar region in SOT.

GENERAL RESEARCH, COURSEWORK AND TEACHING CAPABILITIES: (250-500 words)
TERA scientists combine practitioner's knowledge of the issues and pitfalls involved in development of chemical and human health risk assessments, together with cutting-edge toxicology expertise to develop state-of-the-art assessments. TERA applies a collaborative philosophy that emphasizes partnership building, allowing us to expand our pool of expertise, build on multiple perspectives, and ensure the use of the best science to address pressing science and science policy issues. Our research seeks to enhance the use of data on mode and mechanism of action to inform qualitative and quantitative aspects of risk assessment, by designing targeted studies and decision frameworks to address key mode of action (MOA) questions, incorporating biomarker data to extend the dose-response curve using advance physiologically-based pharmacokinetic (PBPK) models and biologically-based dose-response (BBDR) modeling approaches and developing approaches to evaluate health risk assessment for potentially-susceptible populations and other areas of uncertainty in risk assessment. These strengths form the basis for our development of independent and science-driven analyses for a range of risk assessment needs, including environmental and occupational chemicals, pharmaceuticals, food, biotechnology, and medical devices. Our research and support areas include:

- Screening-level assessments and hazard and risk ranking
- Comprehensive in-depth evaluations for reference/safety dose derivation and cancer risk of pharmaceuticals, cosmetics, and chemicals
- Occupational risk assessments, including occupational exposure limit (OEL) development
- Risk methods and framework development in dose-response modeling, mixtures risks, mode of action evaluation techniques, and special issues such as children's risk
- Technical support for the pharmaceutical, biotechnology, and medical device industries in residues and active moieties assessments
- Application of advanced dose-response techniques, including benchmark dose, threshold of toxicological concern (TTC), quantitative structure-activity relationship (QSAR), read-across, etc.
- Mathematical modeling of complex biological processes using physiological-based pharmacokinetic (PBPK) models and pharmacodynamic (PD) or biologically-based dose-response (BBDR) modeling

TERA's mission is to protect public health. To magnify our abilities to do so, we have developed training programs to provide other scientists around the world with the knowledge and tools to evaluate toxicity and conduct chemical risk assessments. We have developed an intensive, in-depth, hands-on training in hazard characterization and dose-response assessment for human health risk assessments. The course, with emphasis on dose response assessment, has been presented to various audiences in the US and elsewhere (e.g., Canada, Brazil, China, Turkey, and Australia). Our scientists have also participated in training courses in collaboration with the African Society for Toxicological Sciences (ASTS), the International Union of Toxicology (IUTOX), and the Society for Risk Analysis (SRA) to present training in Nigeria and South Africa and training to African scientists. These courses are designed to provide systematic or targeted training in current assessment practices as well as in the latest methods in human health and environmental chemical risk assessments. The goal is to train scientists, policy makers, regulatory agents, and health safety and environmental coordinators in government, industry, academia, and other organizations.

BROADENING THE REACH AND IMPACT OF TOXICOLOGY GLOBALLY IS ONE OF SOT'S STRATEGIC GOALS.

Please identify any relevant global outreach/collaborative activities in which individual faculty members, department, or the institution as a whole have been engaged: (250-500 words)

One of TERA's goals is to expand our reach to other countries, particularly less developed countries that have significant public health problems that may benefit from toxicology and risk assessment information and training.

- TERA provides a free data base of risk values on the Internet (available through NLM's TOXNET). This includes risk values from multiple countries and organizations and is a valuable resource for use by risk assessors around the world.
- TERA has conducted risk assessment training in a number of countries outside of North America, including China (2007), South Africa (2009, 2019), Brazil (2010), Turkey (2012), Australia (2012), Nigeria (2012), Indonesia (2014), and Egypt (2017). In addition, we annually offer our week-long course twice in the US and have had many participants from other countries participate in these.
- We have done project work for government agencies and companies in many countries outside of North America, including South Africa, Europe, Australia, China, Japan, and New Zealand.
- TERA scientists (e.g., Dr. Michael Dourson) participate in WHO and IPCS activities and committees.
- TERA scientists routinely present at international, national, and regional meetings to share our work broadly with others.
- Our Staff also volunteer their time to review scientific papers for peer-reviewed journals and write journal articles and book chapters for the risk assessment community worldwide.
- TERA staff also work with sponsors and colleagues across the globe to improve the science of risk assessment.

If this application is successful, which resources and programs within SOT do you plan to share with your Scholar and why? (250-500 words)

Prior to attending the 2022 Annual Meeting, TERA will work with the Scholar to take advantage of the several resources programs within SOT. The following will be earmarked for pursuing:

- Continuing Education Courses. The Scholar will attend both the morning and afternoon courses. Of particular interest would be courses offering principles on human health risk assessment. The Scholar will update his or her knowledge on how to conduct risk assessment, the process used by regulatory agencies worldwide to estimate the nature and probability of adverse health and environmental effects in humans and ecological receptors from chemical contaminants and other stressors that may be present in the environment. Another potential course will be on chemical safe assessment or any other course of relevance to the Scholar.
- Plenary sessions, workshops, platform and symposium sessions, round-table discussions, poster sessions as well as informational sessions. This will expose the Scholar to cutting-edge methodologies and technological advances and would be of use in developing research by the Scholar.
- Specialty Sessions. Of particular interest would be Food Safety Specialty Section to learn about the state-of-art research involving food safety and regulations and interact with members of this Section; Regulatory and Safety Evaluation Specialty Section (RSESS) to learn about development of sound governmental policies and regulations based on contemporary scientific knowledge arising from the disciplines encompassed by toxicology;

and Risk Assessment Specialty Section (RASS) to learn about current issues, challenges and tools for risk assessment and advances in the science of risk assessment.
- Meeting with experts in the Scholar's field. TERA and the Scholar will identify relevant experts to meet with at the Annual Meeting. We will schedule such meetings ahead of the Annual Meeting. The purpose is to discuss future collaborations with them or for them to become resource people for the Scholar.
- Membership in Specialty Sections and Regional Chapter. The Scholar will be encouraged to join a Specialty Section and a Regional Chapter. This will enable the Scholar to be abreast with what is happening with the Section and Chapter of choice.
- Post-Annual Meeting Webinars, on-line courses, etc. The Scholar will be encouraged to participate in SOT-sponsored webinars and workshops and on-line courses as well as webinars organized by the Specialty Sections and Regional Chapters to be abreast with new knowledge in toxicology and risk assessment.

PROPOSAL FOR ENGAGEMENT WITH SCHOLAR'S INSTITUTION (250-500 WORDS)
The benefits of a face-to-face exchange is such that the scholar and host can best establish a collaborative working partnership. Interacting directly at your institutions provides a holistic and unrehearsed interaction that can best provide attention of the needs and desires for furthering toxicology in the developing region. Although technological advances have allowed us to all collaborate during the pandemic and times of geopolitical unrest, there is no equal substitute for face-to-face interaction over the course of several weeks.

TERA is well known, among others, for the development of technical chemical risk assessment products and services, for developing risk assessments where there is the need, for teaching toxicology and risk assessment nationally and globally, and for helping and enabling groups in developing countries with limited resources and access to toxicological and risk assessment expertise. TERA also promotes collaborative efforts with specialists and organizations dedicated to supporting public health protection by improving the process, research, and efficiency of risk assessment. As a leader in toxicology and human health risk assessment, TERA will engage the scholar's institution in developing expertise in toxicology and human health risk assessment and to be a resource for faculty and students. In collaboration with the scholar's institution, we intend to help the institution to develop semester courses in toxicology and risk assessment for undergraduates and/or graduates, with local, regional, national and/or international experts, including TERA scientists, participating as guest lecturers either in person or via Zoom or any other platform. A similar international workshop was held last year (2020) in collaboration with the 2019 global scholar we hosted. The scholar's institution will benefit from TERA's support and networking opportunities to advance the teaching of human health risk assessment and the institution is expected to serve as a peer role model or mentor for risk assessors in the host country and beyond. TERA will also engage the institution to be at the forefront in developing expertise not only in the host institution but in the host country and beyond. This will include organizing local, national, and international workshops with funding from other like-minded organizations. TERA will also encourage the scholar's institution to collaborate with researchers across disciplines within and outside of the institution, including governmental and non-governmental organizations. Reaching out to these scientists will provide the platform for brainstorming ways to promote human health risk assessment, development of solutions to country-specific risk assessment issues, resulting in the protection of public health.

PLEASE DESCRIBE WHAT CONTENT AND MATERIALS YOU AIM TO SHARE WITH YOUR SCHOLAR AND OVER WHAT TIMEFRAME (HOURS, DAYS, WEEKS) THEY WILL BE SHARED. INDICATING THE AUDIENCE, SUCH AS TRAINEES, FACULTY,

COLLABORATORS OF THE SCHOLAR, IS HIGHLY ENCOURAGED. ALTHOUGH THE SCHOLAR IS NOT YET PAIRED, AN ITEMIZED, ESTIMATED BUDGET (UP TO $5000) SHOULD BE PROVIDED TO ENSURE RESOURCES FOR MATERIALS, TRAVEL AND LODGING ARE DIRECTED APPROPRIATELY FOR YOUR VISIT TO THE SCHOLAR'S INSITUTION.

If, for whatever reason, some content will be presented virtually, cite rationale and how it will be delivered/shared (e.g., videoconference, webinar, video chat, etc.) and over what time frame. Of course, with virtual materials and discussions, budgets should be adjusted accordingly.

As a requirement of the Global Senior Scholar Exchange Program (GSSEP), we intend to visit the Scholar's institution for one week. Before the Scholar returns to his/her institution after the four weeks, we will map out the path forward. While at TERA, the Scholar would have interacted with several leading toxicology and risk assessment scientists in industry, academia, and governmental organizations. This is expected to result in future collaborations with the experts in the fields of toxicology and risk assessment. We will spearhead export of toxicology and risk assessment as they are practiced in developed countries to the Scholar's home country and other surrounding developing countries. The Scholar's visit will begin an effective education and training of scientists and regulators in the home country in risk assessment and toxicology. TERA will accomplish this by conducting our signature "Dose-Response Assessment Boot Camp", a unique 5-day intensive hands-on training in hazard characterization and dose-response assessment for individuals in the risk assessment or toxicology field. At this training, the Scholar and colleagues from the institution and governmental institutions would present on the issues of importance to them. We intend to meet with ministries and institutions in the home country who are involved in public health and environment to initiate programs that would train students and practitioners in the long term. Following our visit to the Scholar's institution, interactions would be via videoconferencing and video chat but at no additional cost to GSSEP or the Scholar.

The following agenda will be followed for the one-week training course at the Scholar's institution:
Monday: Overview of Boot Camp, Overview of Risk Assessment, Noncancer Hazard Characterization, Cancer Hazard Characterization, and Homework Assignments.
Tuesday: Noncancer Dose-response Assessment, Cancer Dose-Response Assessment, Mode of action, and Inhalation Dosimetry.
Wednesday: Oral Dosimetry, Introduction to BMD and DR Modeling, Guest Lecturer, Introduction to Toxicokinetics, and Physiologically Based Pharmacokinetics (PBPK).
Thursday: Chemical-Specific Adjustment Factors (CSAFs), Guest Lecturer, and International Advances.
Friday: Small Group Presentations and Class Peer Review, Course Summary and Evaluation, and Presentation of Certificates.

SOT may contact applicants to provide information about programs of potential interest.
SOT privacy policy.