

Regulatory and Safety Evaluation

ANNUAL REPORT

May 1, 2018 to April 30, 2019

I. Officers/Committees:

<u>Officers</u>	<u>2017-2018</u>	<u>2018-2019</u>
President:	Edward V Ohanian	Marie C Fortin
Vice President:	Marie C Fortin	Anne Elizabeth Loccisano
Vice President-Elect:	Anne Elizabeth Loccisano	Amy L Roe
Secretary/Treasurer:	Amy L Roe	April O'Connell
Past President	Michael L Dourson	Edward V Ohanian
Councilors:	April D Lake	Norman Kim
	Norman Kim	Haitian Lu
PDA Representative:	Gregory James Smith	Gregory James Smith
GSLC Representative:	Monique TaShara Williams	Brett Winters

RSESS Committees:

RSESS 2019 Scientific Program Committee: Robert Budinsky, Mary Ellen Cosenza, Santhini Ramasamy, Angelique Braen, Ryan Hamilton, Maggie Dempster, Dave Allen, Brian Hughes

RSESS 2019 Awards Committee: Anne Loccisano, Amy Roe, April O'Connell, Ryan Hamilton, Vijay Kannappan, Logeswari Ponnusamy, Aishwarya Sarma, Nikaeta Sadekar, Bindu Prabhakar

Ad hoc Webinar Committee: Ryan Hamilton, Jessica Jimenez, Norman Kim

II. Activities:

2019 SOT Annual Meeting RSESS Reception was held in Baltimore, Maryland. Approximately 150 people were in attendance. RSESS President, Marie Fortin, called the meeting to order at 6:30 PM on March 11, 2019, and the executive committee proceeded with the business portion of the meeting.

6:00 – 6:30 Networking
6:30 – 7:00 Business Meeting
 Officer Introductions
 Financials and Endowments
 Scientific Program Committee Update
 Awards
 Announcements

7:00 – 7:30 Open meeting
 Great debate
 Passing of the gavel
 Open floor

RSESS recognized and awarded graduate students, postdoctoral scholars, and the best paper of the year.

Regulatory & Safety Evaluation Best Paper Award Winner

Daniele Wikoff, PhD, ToxStrategies

“Benefit-risk Analysis for Foods (BRAFO): Evaluation of Exposure to Dietary Nitrates” Food Chem Toxicol. 2018 Oct; 120:709-723

RSESS Graduate Student Excellence Awards

Sarah Faure, University of Montreal, Canada

“Analysis of Environmental Chemical Exposure of the Canadian Population from the Canadian Health Measures Survey in a Risk Based Context”

Sarah Burnett, Texas A&M University

“Enabling Assessment of Cardiotoxicity Hazard for Environmental Chemicals Using an In Vitro Human Population Model”

RSESS Postdoctoral Excellence Awards

Wei-Chun Chou, Kansas State University

“Bayesian Evaluation of Physiologically Based Pharmacokinetic (PBPK) Modeling for Perfluorooctanesulfonate to Characterize the Interspecies Uncertainty between Mice, Rats, Monkeys and Humans: Development and Performance Verification”

Yi-Hsien Cheng, Kansas State University

“Assessing Delivery Efficiency of Nanoparticle to Tumors in Tumor-Bearing Mice Using a Physiologically Based Pharmacokinetic Modeling”

RSESS “Great Debate”

A. Wallace Hayes moderated the debate on “The Health and Societal Impact of Cannabis Use”. Two debaters were Ryan Vandrey of Johns Hopkins University for the con perspective and Peter Pressman of the Daealus Foundation/PolyScience Consulting for the pro viewpoint.

2019 SOT Annual Meeting Courses/Sessions:

There were 145 sessions proposals in 2019, of which 43 asked for RSESS endorsement. Three asked for primary endorsement from RSESS and twenty-seven and thirteen asked for secondary and tertiary endorsement, respectively.

Overall, there were endorsement requests for fifteen symposia, fifteen workshops, five information sessions, seven continuing education, and one education and career development session; of which six symposia, four workshops, three continuing education, and two information sessions were selected into the program.

Some of the key sessions were:

- Current Dose-Response modeling Strategies and Applications in Chemical Risk Assessments
- Federal Efforts in Rapidly Assessing Hazard and Risk to Emerging Threats and Emergency Response
- Shifting Currents in Predictive Toxicology and Safety Evaluation with In Vitro and Alternative Approaches
- Potential Alternatives to Systematic Review: Evidence Maps and Scoping Reviews
- Species Relevance: Approaches to Determine the Most Relevant Species for Safety Assessment of Pharmaceutical Products
- When “Natural” Is Not Synonymous with “Safety”: Toxicity of Natural Products Alone and in Combination with Pharmaceutical Agents
- Understanding the Utility of In Vitro Developmental Toxicity Assays and Building Integrated Testing Strategies

RSESS SOT Mentoring Events:

While RSESS is one of (if not) the largest specialty section of SOT, it has very limited trainee memberships (graduate students and postdocs represent approximately 5% of our members). Therefore, in order to increase the visibility of the careers in the fields of regulatory and safety evaluation, RSESS co-organized two joint mentoring events at the SOT Annual Meeting.

The **Risk Assessment Specialty Section (RASS) and RSESS** joint mentoring luncheon was held on Wednesday March 13 from 12:00 – 1:15 PM. Mentors from a variety of roles across industry, consulting, academia, and government participated and their biosketches were emailed to the attendees prior to the event. The event was completely booked with more than 15 mentors and 35 mentees.

The **Molecular and Systems Biology (MSBSS) and RSESS** joint mentoring reception was held in collaboration with Mechanisms, In Vitro and Alternative Methods (IVAM), Computational Toxicology (CTSS) Specialty Sections, and The American Society for Cellular and Computational Toxicology (ASCCT) on Monday March 11, 2018 from 7:30 – 9:30 PM at Tír Na NÓg. Approximately 40 mentors from industry, academia, government, and non-profit; and 150 graduate students and postdoctoral fellows had the opportunity to network in a fun and relaxed environment.

Overall, these highly successful cross-sectional mentoring activities provided trainees with a better picture of the complete landscape of careers in toxicology.

Endowment Fund Details:

Given that the current endowment fund was in spent down mode, the RSESS established a new fund in the hope that it achieves the permanently endowed status within the dictated 3-year period. The Future of Regulatory and Safety Evaluation Endowment Fund was thus established in September 2018. This fund encourages research and training, scientific progress, collaboration, and the modernization of the fields of safety evaluation and/or regulatory toxicology. The fund is aligned with the Regulatory and Safety Evaluation Specialty Section and will be used primarily to provide a monetary award(s) to graduate students and/or postdocs based on scientific excellence and scientific progress toward novel, better, and fit for purpose, modern approaches to safety evaluation and/or regulatory toxicology. It can also be used to help provide support for Society of Toxicology programs that help foster sharing of knowledge related to scientific progress in the fields of safety evaluation and/or regulatory toxicology. The Fund recognizes that safety evaluation in the field of toxicology is undergoing a paradigm shift to a predictive, mode-of-action-focused discipline and that advancing the science of safety evaluation and regulatory toxicology is a sine qua non condition to creating a safer and healthier world.

Newsletters:

RSESS published two newsletters during the past year – Summer 2018 and Winter 2019. In addition to providing our members with information regarding their SS activities and update, each newsletter included a Hot Topic article cowritten by our graduate student and postdoctoral representatives, Brett Winters and Gregory Smith. The first one was titled: ***Prop 65: Roasting Coffee Shops on Acrylamide***, and the second one was titled: ***High Time for Regulatory Toxicologists in Recreational Cannabis?*** The newsletters are available on our website.

RSESS Webinars:

“Assessment of Adversity and NOAEL in Toxicology Studies to Support Regulatory Decisions” on October 10, 2018

Findings in nonclinical toxicity studies are interpreted as either adverse or nonadverse, and can be subsequently used to define the no-observed-adverse-effect level (NOAEL). Recommendations (best practices) were provided by the Society of Toxicologic Pathology’s Adversity Working Group for making consistent interpretations of test article-related effects on adversity and determination of NOAEL in nonclinical toxicity studies (Kerlin et al., Toxicologic Pathology 44(2), 2016).

- Vincent P. Meador, DVM, PhD, DACVP (Pacific Tox Path, LLC, and a member of a task force for the STP to define adversity and its use in safety studies) presented a review of best practices and points-to-consider on defining adversity and NOAEL in toxicity studies.
- John L. Vahle, D.V.M., Ph.D., DACVP (Senior Research Fellow at Eli Lilly) provided a few case studies on the interpretation of toxicity studies of small and large molecules.

The webinar was very well attended.

Other Specialty Section 2018-2019 Activities:

RSESS Website Update:

The RSESS worked through a massive overhaul of the website. The website was dated and in dear need of an update. Brett Winters led the effort and came up and together with SOT staff, we came up with a streamlined design. While the work was carried through during the 2018-2019 term, the site is about to launch now.

RSESS Logo Update:

The RSESS also update its logo in 2019, just in time for the Annual Meeting. The new logo highlights the importance of Regulatory and Safety Evaluation at the cross-roads of toxicology, public health, and regulatory activity.



RSESS Pin Update:

The RSESS also created a pin which was distributed to the members during the mentoring events and the reception. This pin was created using the above logo and will help increase the visibility of RSESS within SOT as well as a sense of pride and belonging to those who wear it. The members of RSESS as those whose work is fundamental or creating a safer and healthier world.