

July 2015

EIC Survey Deadline Extended! The deadline to submit your Emerging Issues Prioritization Survey has been extended to <u>10 August 2015</u>. During the HESI Annual Meeting in June, the Emerging Issues Committee (EIC) presented the 2015 topics selected for prioritization by stakeholders that would benefit from HESI's focused, multi-sector collaborative approach. Proposal submitters presented on the following topics: 1) Models/Tests to Assess Stem Cells as Therapeutic Agents: Using Imaging Technology to Evaluate Stem Cell Safety, Mode of Action, and Efficacy; and 2) Transforming Exposure Science Through a Strategic Integration of Emerging Technologies and Big Data to Improve Predictive Exposure Capabilities. Both proposals are available on the <u>HESI website</u>. HESI stakeholders are being asked to rank these proposals during the summer. You are invited to submit your ranking online via <u>Survey Monkey</u> by 10 August 2015. The EIC will meet in the fall of 2015 to discuss which, if any, proposals will be selected for further action. For more information, contact Ms. Jennifer Pierson (jpierson@hesiglobal.org).

Thank You to Nancy Doerrer! HESI would like to recognize Ms. Nancy Doerrer, Associate Director, on the occasion of her retirement from HESI in June. Nancy has been with HESI since April 2002 and progressed from Scientific Program Manager, to Senior Manager, to Associate Director. She leaves behind an indelible positive impact on our staff and members as well as all of the programs on which worked. Nancy was particularly instrumental in developing HESI's Emerging Issues process and Program Strategy and Stewardship initiatives over many years. Her role in helping to design and then lead the new Program Associate staff model has been transformative for HESI. Nancy's scientific and organizational leadership has long been part of HESI's success. We will miss working with our friend and colleague tremendously, but we hope you join us in wishing her the best in this next chapter.





Congratulations to Dr. Lau! We congratulate Dr. Serrine Lau, who was recently awarded the George H. Scott Award at the Summer Toxicology Forum Meeting in recognition of her outstanding contributions to developing and applying the science of toxicology. Dr. Lau has been an active member of HESI since 2008 and a member of the HESI Board of Trustees since 2011.

New Project on Nonclinical Neonatal Pediatric Animal Models. The DART Technical Committee recently adopted a new project through the Emerging Issues process on the topic of nonclinical efficacy and safety studies to support neonatal therapeutics. The project aims to 1) identify major gaps in pre-term and term neonatal drug developmental and neonatal animal models of human disease and 2) address how to best leverage neonatal nonclinical models to support safety and proof of concept for human neonatal disease. The project ultimately aims to develop relevant study designs and data that can be obtained from nonclinical models. Similar to other new Emerging Issues subcommittees, you do not have to be a member of the DART committee to participate during the first year of the project. We welcome new partners who will bring a fresh perspective to the project. Contact Connie Chen (cchen@hesiglobal.org) if you have questions or are interested in participating.

UPCOMING EVENTS

Pregnancy and Lactation Labeling Workshop. If you weren't able to attend the April workshop on FDA's Pregnancy and Lactation Labeling Rule, you haven't missed out. The DART Technical Committee is taking the lessons learned from their recent US-based workshop and is sponsoring a European-based workshop to be held in conjunction with the European Teratology Society (ETS) Annual Meeting. The satellite workshop will be held on 2–3 September 2015 in Amsterdam, Netherlands. For more information, visit the ETS website <u>here</u> or contact Dr. Connie Chen (<u>cchen@hesiglobal.org</u>).

HESI in Europe – Upcoming Meetings & Presentations:

- 25 August 2015, European Environmental Mutagenesis and Genomic Society Meeting Prague, Czech Republic. Dr. Henghong Li, Georgetown University, will present, "Cell-based application of a genomic biomarker to address potentially irrelevant positive findings in chromosome damage assays," on behalf of the HESI Genomics Committee at the <u>EEMGS</u> Annual Meeting.
- 14 September 2015, HESI CITE Lecture at EUROTOX Porto, Portugal. Ms. Syril Pettit, HESI Executive Director, will chair the HESI CITE session at the 2015 EUROTOX meeting, where Dr. John K. Colbourne, Chair of Environmental Genomics, School of Biosciences, University of Birmingham, UK, will present "Phylotoxicology: breaking the artificial divide between human- and eco-toxicology."
- 24 September 2015, 13th European Congress of Toxicologic Pathology Surrey, UK. Dr. Philippe Couttet, Novartis will present the HESI Genomics Committee's work, "Enhancing the translational relevance of preclinical studies via profiling of mRNA and microRNA in biofluids and tissue samples" at the joint <u>ESTP/BSTP meeting</u>, University of Surrey, UK.
- Sept 28-Oct 1 2015, Safety Pharmacology Society Meeting Prague, Czech Republic. The HESI Cardiac Safety Committee, Cardiac Biomarkers Working Group will present a poster on "Biomarkers of Hypercoagulability in a Rat Sepsis-Induced Model of Non-Overt Disseminated Intravascular Coagulation (DIC)" at the SPS Annual Meeting.

STAFFING NEWS

Congratulations to Dr. Embry! HESI is pleased to announce that Dr. Michelle Embry has been promoted to Associate Director, Environmental Science. Michelle has been a valued employee at HESI for 9 years and this promotion recognizes Michelle's outstanding contributions as a senior HESI committee manager along with her broad recognition as a sought-after technical expert in environmental science. These recognitions include her election to environmental scientific advisory boards, numerous personal speaking invitations, requests for her expert technical consultation, strong publication record, and more. Her scientific credentials and leadership have already brought many new partners and opportunities to HESI. Congratulations Michelle!



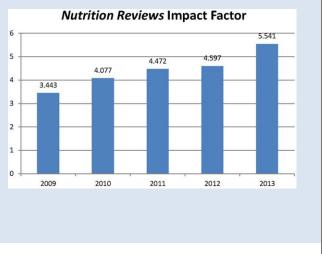
Welcome to Teyent Getaneh! Teyent earned her B.S. in Biochemistry from Virginia Tech, in 2008. In June 2015, she joined HESI as a Scientific Program Associate supporting committees on Neurotoxicology, Protein Allergenicity, Genetic Toxicology, and Imaging in Safety Assessment. Prior to joining HESI, Teyent worked as a GLP Program Coordinator at the Armed Forces Radiobiology Research Institute and as a Program Coordinator at the Naval Medical Research Center, where she provided scientific and program management support in the vaccine development against ETEC bacteria.

PUBLICATION NEWS

The 2014 impact factors for scholarly journals have just been released, and we are delighted to report that ILSI's journal, *Nutrition Reviews*, has risen again in both impact factor and ranking:

- Impact Factor: 6.076 (from 5.541 in 2013)
- Ranking: 4 of 77 (from 5 of 78 in 2013)

The graph to the right shows Nutrition Reviews' trajectory since 2009. These numbers reflect the journal's continued position as the most highly ranked, monthly, all-review journal in its field, and help demonstrate ILSI's firm commitment to the dissemination of the highest-quality scientific knowledge.



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FROM THE EXECUTIVE DIRECTOR

The June 26 issue of *Science* magazine features several articles focused on reproducibility in science ("<u>The Cancer Test</u>," "<u>Solving</u> <u>Reproducibility</u>," etc.). While most agree that repeatable science is critical for forward progress in any research field, the optimal approaches for supporting this outcome are neither simple, uniform, nor self-evident. Further, it seems likely that this issue will gain further prominence in both the scientific and lay communities. HESI's long history of building collaborative initiatives with a strong emphasis on reproducibility as an endpoint means we are well positioned as both thought-leaders and practitioners in this evolving space.

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