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# ILSI Health and Environmental Sciences Institute: HESI

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*Official  
Representatives  
Business Meeting  
'Assembly Meeting'*

*10 June 2014  
Washington, DC*

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Health and Environmental  
Sciences Institute

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# AGENDA

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- Welcome (5 min)
- Official Rep Training (30 min)
- Business Update (10 min)
- Vote (5 min)
- Open Discussion (*to end and as we grab lunch!*)






*A New Leaf*

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# HESI 'Official Representative Training

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*Understanding  
and optimizing  
your roles in  
HESI*

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# What will we learn?

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- HESI structure and governance;
- Roles and responsibilities as an Official Rep (OR);
- Maximizing your value for HESI participation.



# Get ready!

**When we finish today, you should be able to define the following terms...**

- ✓ Official Representative
- ✓ HESI Assembly
- ✓ HESI Member
- ✓ HESI Sponsor
- ✓ Trustee



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# HESI 'Official Representative' Training

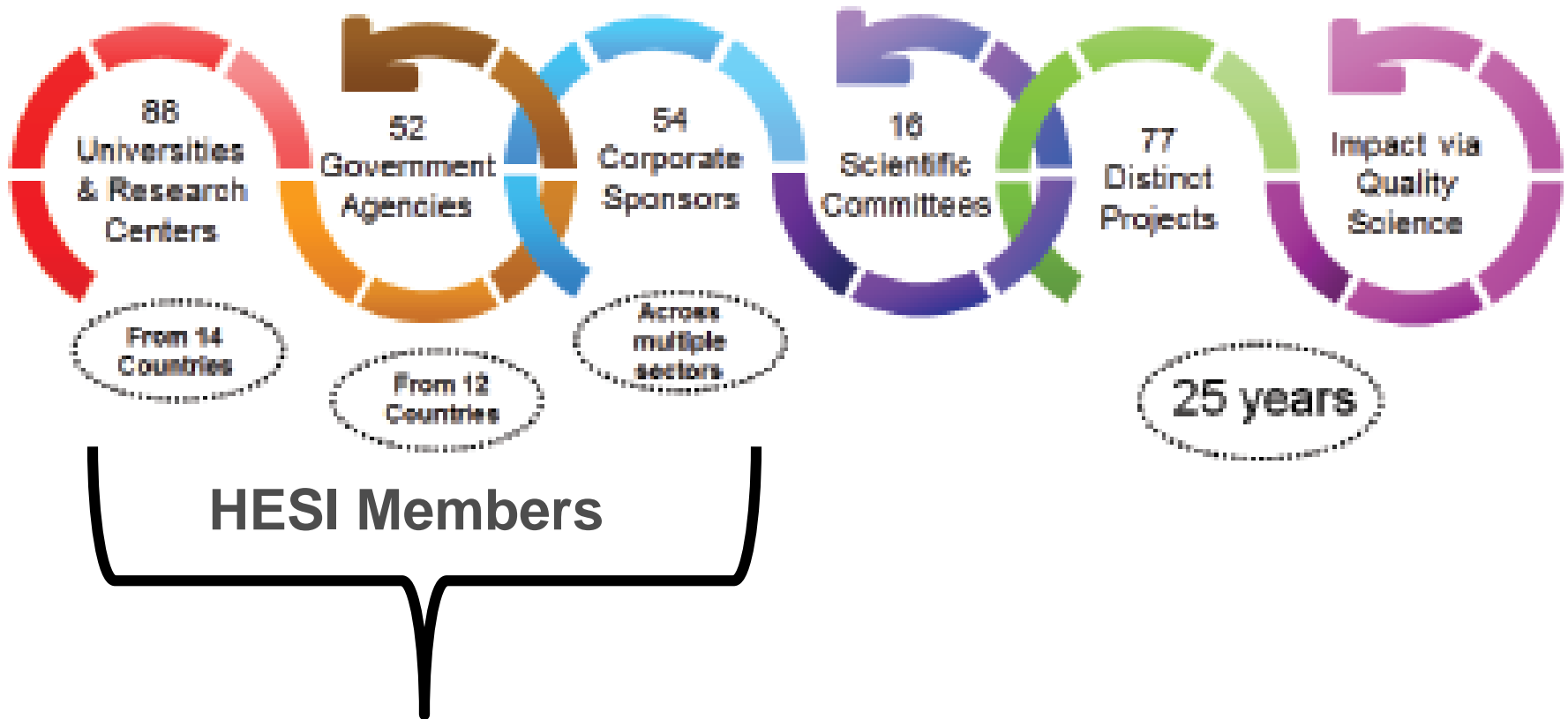
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## *Section 1: Structure & Governance*

# HESI by the Numbers

## HESI by the Numbers







# What kind of organization is HESI?

- Non-profit, global, 501(c)(3)
- Charitable entity, science for public benefit.
- Focus on tripartite+, transparency, credibility
- No product or company specific issues.
- No lobbying or direct influence on policy.

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# I hear a lot about 'ILSI' – What's that?

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International Life  
Sciences Institute:  
Formed in 1978,  
regional branches  
focused on food and  
nutrition issues.



HESI established in  
1989 as a global  
branch of ILSI.



# The ILSI Network

- HESI, ILSI Research Foundation, and Regional ILSI Branches constitute the ILSI Network



- HESI separately incorporated w own governance and financial oversight.

## Regional Branches

- ILSI Argentina
- ILSI Brasil
- ILSI Europe
- ILSI Focal Point in China
- ILSI-India
- ILSI Japan
- ILSI Korea
- ILSI Mexico
- ILSI North America
- ILSI North Andean
- ILSI South Africa
- ILSI South Andean
- ILSI Southeast Asia Region
- ILSI Taiwan

# The ILSI Network

ILSI Global .



# The ILSI Network ILSI Regional Branches

Local members and efforts. Largely food & nutrition focus.



# The ILSI Network

## ILSI Research Foundation –



The Center for Environmental Risk Assessment (CERA)  
The Center for Integrated Modeling of Sustainable Agriculture & Nutrition Security (CIMSANS)  
The Center for Risk Science Innovation and Application (RSIA)  
The Center for Safety Assessment of Food and Feed (CSAFF)

### Regional Branches

ILSI Argentina  
ILSI Brasil  
ILSI Europe  
ILSI Focal Point in China  
ILSI-India  
ILSI Japan  
ILSI Korea  
ILSI Mexico  
ILSI North America  
ILSI North Andean  
ILSI South Africa  
ILSI South Andean  
ILSI Southeast Asia Region  
ILSI Taiwan

# How is HESI Governed?

HESI Board of Trustees & Staff are stewards of:

- By-laws
- Anti-trust policy
- Conflict of Interest declaration
- Articles of Incorporation
- Data Sharing Policy (not a legal document)

Participating organizations are not bound to HESI by any type of standing confidentiality agreements



# How does HESI ensure balance in its governance?



- Public > Private on HESI Board
- Board Chair and Vice-Chair always public sector

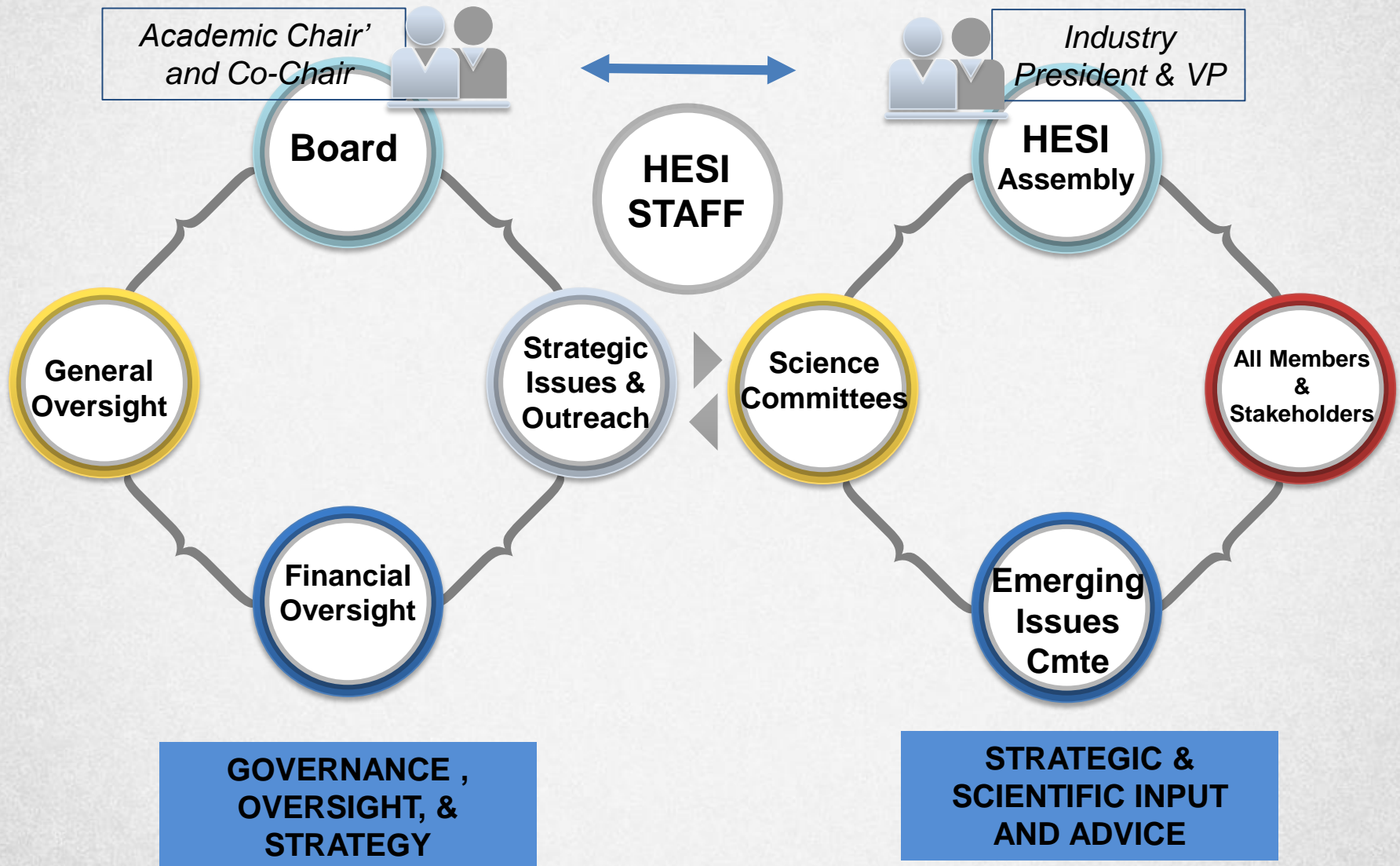
**Public Sector Scientists  
at HESI =  
academic,  
government, NGO,  
research institute,  
clinical medicine, etc.**

## Executive Committee of the Board

**Chair – public sector  
Vice Chair – public sector  
President - private sector  
Vice President – private sector  
Secretary – public or private  
Treasurer – public or private  
+ 2-4 members at large (trustees)**



# HESI Governance and Input Structure



# Meet the HESI Staff



**Nancy Doerrer, MS,  
Associate Director**



**Syril Pettit, MEM,  
Executive Director**



**Michelle Embry, PhD  
Senior Scientific  
Program Manager**



**Raegan O'Lone, PhD  
Senior Scientific  
Program Manager**



**Cynthia Nobles,  
Branch Administrator**



**Brianna Farr,  
Science Program  
Associate**



**Alex Keller,  
Science Program  
Associate**



**Connie Chen, MPH, PhD  
Scientific Program  
Manager**



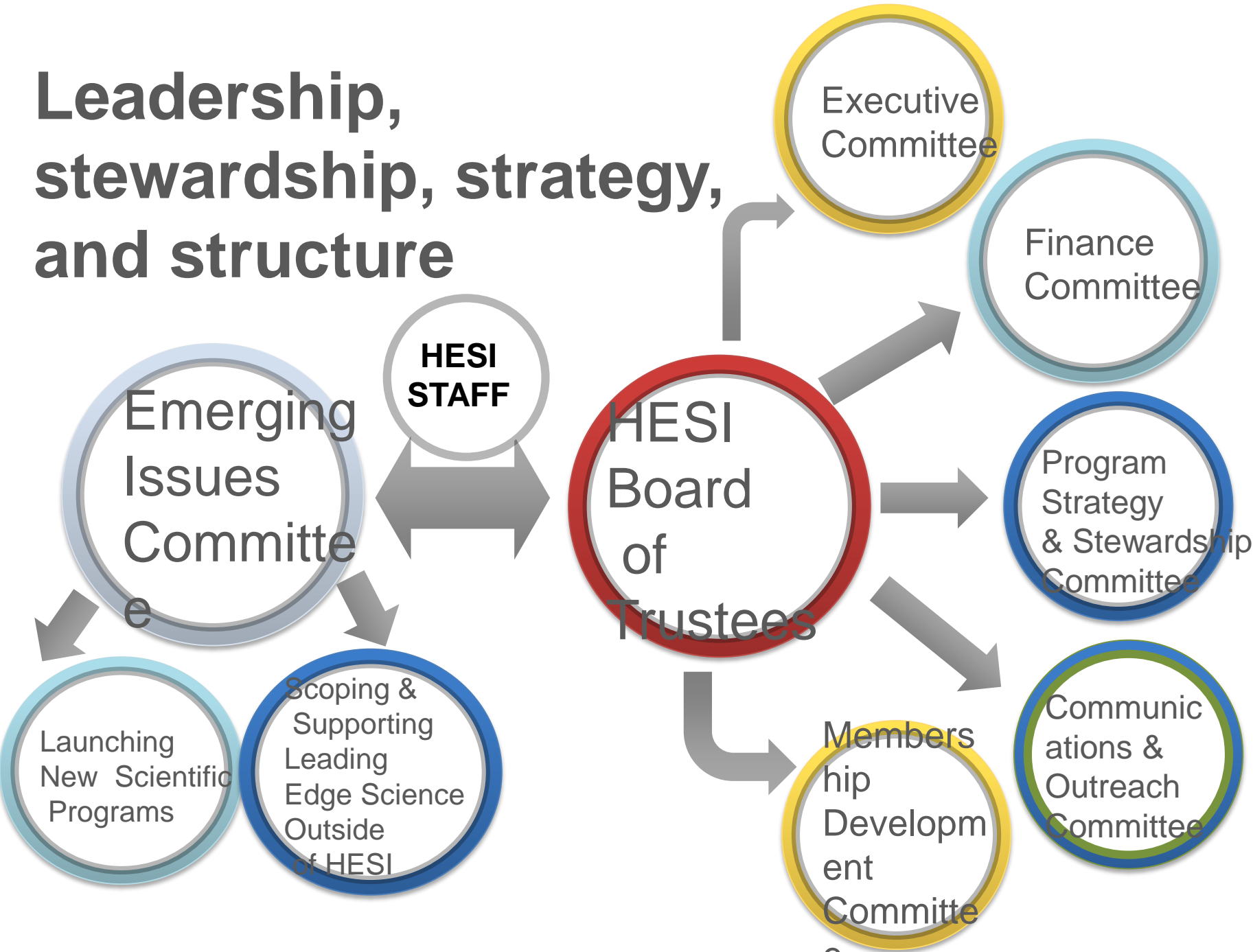
**Jennifer Pierson, MPH  
Scientific Program Manager**



**Jennifer Tanir, PhD  
Scientific Program Manager**

**Connie Chan-Le  
Science Program Associate**


# Leadership, stewardship, strategy, and structure



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# HESI 'Official Representative' Training

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## *Section 2: Roles & Responsibilities as an OR*



**I'm an Official  
Representative...  
What does that mean?**



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# First, the formal stuff.

## As a HESI OR you...

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- Are a member of HESI's Assembly;
- Your organization's official Vote!
- Receive the invoices
- Liaison to HESI staff



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# HESI 'Official Representative' Training

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## *Section 3: Value and Involvement*



In addition to voting  
and paying the bills...

How else can I  
contribute as an OR?



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# Be a Voice for your Organization!

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- Solicit Ideas for Projects
- Pool and Share Priorities
- Get the word out!





HESI



**Take Action & Get Involved**

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# Thank you!!!

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*For more  
information visit  
[www.hesiglobal.org](http://www.hesiglobal.org)*

*Or contact  
cnobles@hesiglobal.org*

# Are you ready for the quiz?

- ✓ Official Representative
- ✓ HESI Assembly
- ✓ HESI Member
- ✓ HESI Sponsor
- ✓ Trustee



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# Business Update



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ILSI Health and  
Environmental Sciences  
Institute

A black and white photograph of a white piggy bank being held by several hands. The piggy bank is the central focus, with its snout and eyes clearly visible. The hands are positioned around the base and sides of the piggy bank, suggesting it is being presented or supported. The background is dark, making the white piggy bank stand out.

# 2014 Financial Report

(Budget approved by BOT in Jan 2014)

- Overall – Financially stable and healthy
- Clean external audit report.
- Early projections for 2014 of.....
- In Jan 2014, BoT approved use of unallocated Operating Reserve Funds for Strategic Plan Implementation – discussions to follow today.
- New funding allocations to benefit projects
  - FAST Fund
  - Open Access
  - EIC Scoping Funds
  - Global Platforms Initiative
  - Considering Future Leaders Travel Fund

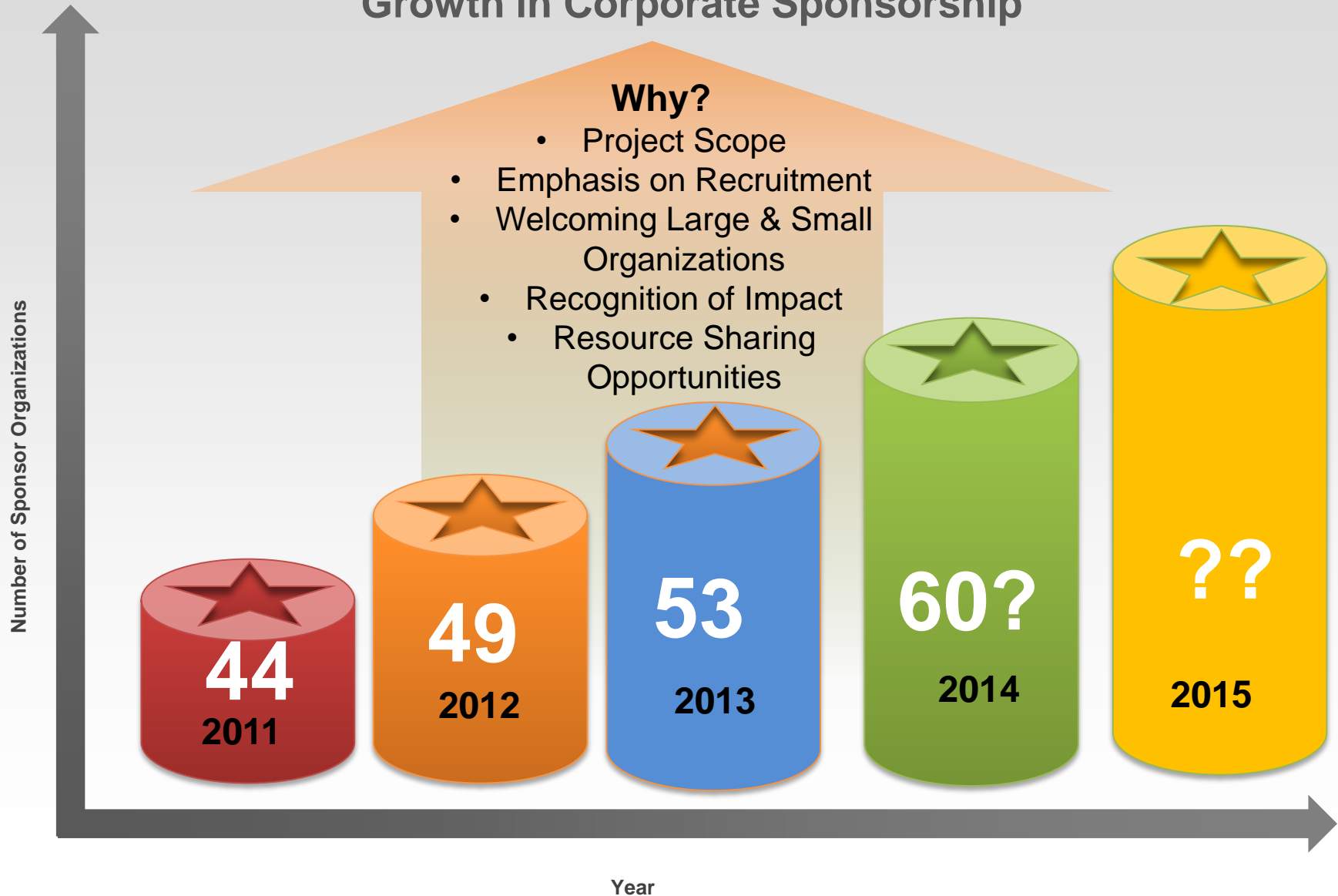


# Reminder of Timelines

- **June:** HESI Board of Trustees to approve 2015 corporate Sponsorship dues - Proposing NO CHANGE.
- **July:** Official Representatives notified of 2015 corp dues
- **July/August:** Scientific Committees set draft assessments
- **September/October:** Scientific Committees finalize budgets
- **October:** Corporate Sponsorship invoices distributed
- **October/November:** HESI Organizational Budget prepared by the HESI Finance Committee.
- **November:** Scientific Committee invoices distributed.
- **January:** HESI Organizational Budget approved by BoT
- **March 1:** All Corporate Sponsorship and Scientific Committee invoices due for payment to HESI.



## Growth in Corporate Sponsorship





# Resources for HESI Programs

## **In-kind resources (analytical and experimental) across sectors in 2013/2014**

- represent millions in pooled research effort;

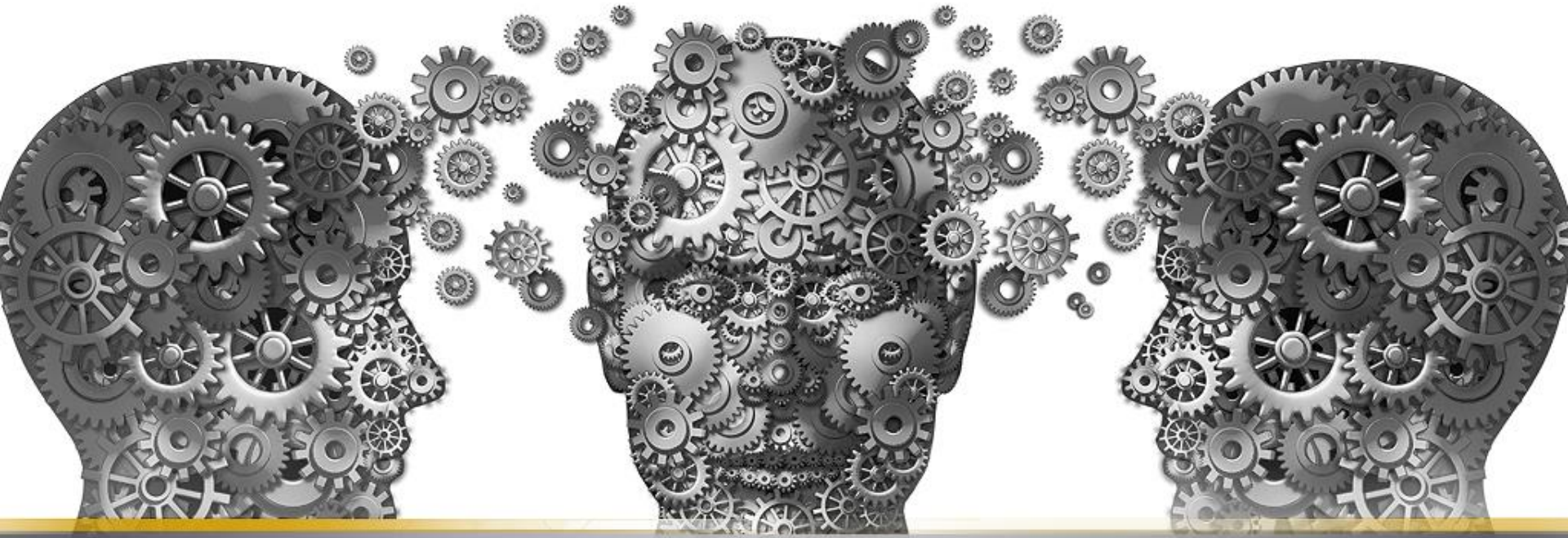
## **Private sector sponsor dollars**

- support infrastructure for program coordination, meetings, outreach, & some outsourced research;

## **Partnered Public Funding for 2013/14**

- Financial contributions from NIEHS, NGOs, for the 2013 Cancer Genomics workshop
- Funding from Environment Canada to support an academic working on research in collaboration with HESI Bioaccumulation Committee;
- Grants from Canada's Environmental Health Science and Research Bureau (EHSRB) Chemicals Management Plan (CMP) Research Program to Health Canada staff for projects conducted in direct collaboration with the HESI GTTC;
- FDA hired internal 'Fellow' to work on data analysis as a partner in the HESI Cardiac Safety ProA project;
- HESI DART Committee and University Utrecht Grant funding supporting a postdoctoral researcher to conduct analyses in support of the DART 2<sup>nd</sup> species project.

# Intellectual Partnership



A Banner Year for HESI...



**SPECIAL NEWS BRIEF**

Your Monthly Update of News and Notes from HESI

HESI NEWS BRIEF: RELEASED DECEMBER 13, 2013

**WHO & ILSI HESI Announce Collaborative Agreement**

In November 2013, the ILSI Health and Environmental Sciences Institute finalized a collaborative agreement with the World Health Organization to jointly develop and maintain a freely-available on-line database of chemical risk assessment training courses. This publicly accessible resource is anticipated to facilitate access to training by providing searchable information on educational opportunities available around the globe. The Training Database Project will provide access to information regarding in-person and online post- and undergraduate, continuing education, and society-sponsored not-for-profit training courses related to human health chemical risk assessment. Via this collaborative agreement, WHO will provide regular input and guidance on the overall database project activities and HESI will provide financial and in-kind support for development and implementation of this collaborative resource. This project is part of the recently-formed WHO Chemical Risk Assessment Network, to which ILSI was invited as an official participant. [For more information on the WHO-HESI Training Database Project or ILSI's](#)

[al.org](#)).

MOU NUMBER

MEMORANDUM OF UNDERSTANDING  
BETWEEN  
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
THE FOOD AND DRUG ADMINISTRATION  
ILSI HEALTH AND ENVIRONMENTAL SCIENCES INSTITUTE

I. Purpose

The United States Food and Drug Administration (FDA) and ILSI Health and Environmental Sciences Institute (HESI) share interests in promoting scientific progress through the exchange of scientific capital to address and reach consensus on scientific questions impacting the development of FDA regulated products and the evaluation of human safety. Both institutions foresee benefits from the mutual exchange of training and research expertise in pharmacology, toxicology and translational science. This

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# 2013-14

## Nominating Committee

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Dr. Laurie Hanson– Pfizer (Chair)

Dr. Kendall Wallace, U Minnesota

Dr. Martin Philbert, U Michigan

Dr. Tim Pastoor, Syngenta

Dr. Herman Autrup, U Aarhus



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# 2013/2014 Nominations Process

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(Bios of nominees are in the Program Book)

**HESI Board of Trustees**  
*(election by Assembly)*

**HESI Emerging Issues Committee**  
*(election by Assembly)*



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# First, thank you for your service to those leaving the Board

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- Dr. Jay Goodman, Michigan State University (since 1997!)
- Dr. Cynthia Afshari, Amgen
- Dr. Robert Rickard, DuPont
- Dr. Hiroyuki Tsuda, Nagoya City University
- Dr. Jiro Seki, Astellas
- Dr. Douglas Wolf, EPA





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# Proposed Re-nominees to HESI Board

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Dr. Scott Belanger, Procter & Gamble

Dr. Ernie Harpur, Newcastle University

Dr. Serrine Lau, University of Arizona

Dr. Charlene McQueen, RTP

Dr. Angelo Moretto, University of Milan

Dr. Timothy Pastoor, Syngenta

Dr. Kendall Wallace, U Minnesota



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# Proposed New Nominees to HESI BOT

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**Keiichiro Sato, PhD**

*Director, Drug Safety Research Laboratories, Takeda Pharmaceutical Company Limited*

**Myrtle Davis, DVM, Ph.D.**

*Chief, Toxicology and Pharmacology Branch Developmental Therapeutics Program Division of Cancer Treatment and Diagnosis, The National Cancer Institute*

**Sonja Beken, PhD**

*Coordinator Non-Clinical Assessors, Coordinator Oncology Division Evaluators, DG PRE Authorisation, Belgium*

**David Brewster, Ph.D., D.A.B.T.,**

*VP and Global Head Drug Safety Evaluation, Global Exploratory Development, Vertex Pharmaceuticals*

**David L. Eaton, Ph.D.,**

*Dean and Vice Provost, The Graduate School, University of Washington*

**Stefan Platz, PhD**

*Global Head of Drug Safety and Metabolism, AstraZeneca.*



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**ACTION:**  
**Election of HESI Trustees**

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**HESI Board of Trustees**  
(election by Assembly)

**We need a motion, a second and a vote**



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# HESI Emerging Issues Committee Nominees 2014

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## Vice Chair Nominee:

**José Manautou, PhD, ATS Fellow**

University of Connecticut (*term ends June 2017*)

## Public Sector Nominees

(*terms end 2017*)

**Suzanne C. Fitzpatrick, PhD, DABT**

US Food and Drug Administration

**Timothy Gant, PhD**

CRCE, Public Health England

**George Gray, PhD**

George Washington University

(*re-nomination*)

**Ronald N. Hines, PhD**

US Environmental Protection Agency

## Private Sector Nominees

(*terms end 2017*)

**Matthew S. Bogdanffy, PhD, DABT, FATS**

Boehringer-Ingelheim

**Jon C. Cook, PhD, DABT**

Pfizer, Inc.

**Andrew Glickman, PhD**

Chevron Energy Technology Company



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**ACTION:**  
**(motion, second, and vote)**

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**Election of  
public and private sector  
Science Advisor nominees  
to the  
HESI Emerging Issues Committee.**



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# Next Steps

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(for informational purposes only)

## **HESI Board Officers**

(to be elected by the HESI Board Thursday)

## **HESI Executive Committee**

(to be elected by the HESI Board Thursday)

## **HESI representatives to the ILSI Board**

(already elected by the ILSI Board in January 2012)



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# Nominees for 2014 HESI Executive Committee (informational)

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- ✓ Dr. Laurie Hanson, President
- ✓ Dr. Tim Pastoor, Vice President
- ✓ Dr. Ken Wallace, Past Chair
- ✓ Dr. Herman Autrup, Chair
- ✓ Dr. Ernie Harpur, Vice Chair (New Nomination!)
- ✓ Dr. Charlene McQueen, Secretary
- ✓ Dr. Serrine Lau, Treasurer
- ✓ Dr. Peggy Guzzie-Peck, Member-at-Large
- ✓ Dr. Brian Berridge, Member-at-Large.
- ✓ Dr. Martin Philbert, Member-at-Large (New Nomination!)



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