A Resource for Science

The ILSI Health and Environmental Sciences Institute (HESI) provides the structure, credibility, and management necessary for successful collaboration amongst scientists from academia, government, research institutes, foundations, and industry to identify and resolve global health and environmental issues.

HESI's focus areas span from basic research and discovery to applied decision-frameworks. All of HESI's initiatives provide fit for purpose science to address contemporary health and safety challenges.

HESI improves public health by generating quality science to support the following:

- Safe and effective medicines;
- Environmental quality and sustainability;
- Accurate and resource-efficient risk assessment; and
- Food safety.

A Network of Experts

Technical programs at HESI offer access to knowledge, experience, and shared resources through a large and international network of scientists. Insights from researchers in Africa, Asia, Europe, North America and South America help make scientific outcomes meaningful across borders and cultures and applicable at regional, national, and international levels.

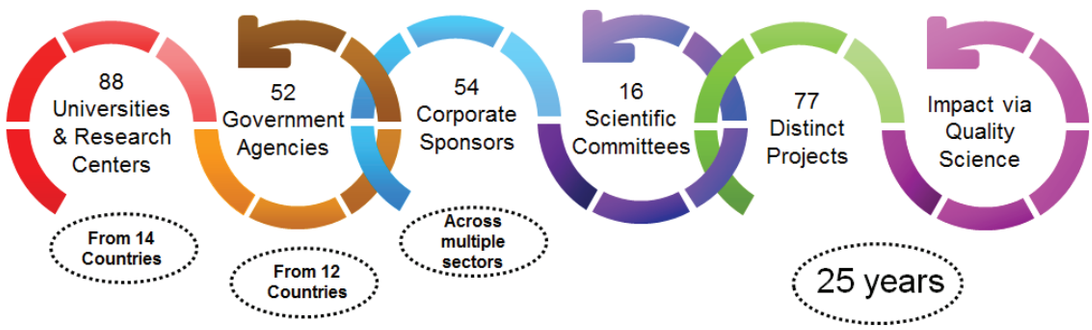
This diversity allows for identification of the high priority cross-cutting issues, ensures balance, drives effective solutions, and establishes critical networks to facilitate the uptake of new science.

HESI's programs are coordinated by scientifically trained professional staff whose technical capabilities, management expertise, and facilitation skills support the development of rigorous and timely outputs.

A Standard of Excellence

For over 25 years, HESI has been a leader in generating the uniquely relevant scientific outputs that result from effective multi-sector engagement. The organization is recognized for its unwavering commitment to scientific rigor and balance of perspectives. HESI's work has been directly utilized by thousands of scientists around the globe including governments, industries, academicians, national research panels, and inter-governmental organizations seeking to improve human and environmental health.

HESI by the Numbers



Recent Initiatives and Strategic Efforts at HESI

HESI: Pillars of Excellence – Supporting Science for a Healthier World

In January 2014, the HESI Board of Trustees approved several new initiatives designed to enhance the impact, global relevance, and expediency of HESI's scientific programs and public health mission.

These initiatives are part of Board-designated Pillars of Excellence (i.e., Knowledge to Application, Global Vision, and Future Leaders). Together, these Pillars define HESI's current efforts and future aspirations for contributions to the scientific community.

Knowledge to Application – Supports positive health impacts via the implementation of efficient and fit-for-purpose scientific programs that engage diverse stakeholders and disciplines. Includes HESI's current scientific committee portfolio and the CITE Initiative (see below).

Global Vision - Supports global HESI initiatives that recognize that science has no borders. Enhances HESI's role as an international organization by emphasizing global reach for HESI science within HESI committees as well as via independent, strategic interactions with global entities such as WHO, OECD, and others.

Future Leaders – Supports training, education, awards, and mentorship to foster the skills needed to meet the challenges of modern safety sciences. Enhances creation of career-development opportunities through engagement with HESI scientific committees. Encourages outreach with other scientific foundations/organizations to foster access to cross-disciplinary career development opportunities.

HESI CITE – Combining Interdisciplinary and Translational Expertise

In December 2012, HESI enhanced its role in facilitating the translation of science from research to application with the launch of the CITE Initiative. Via CITE, HESI has gained recognition as both a thought-leader in and facilitator of best practices for effective collaboration to benefit public health. CITE seeks to bring novel approaches for innovation, education, and efficiency to the practice of translational science.

Over the past 18 months, CITE-sponsored workshops, symposia, publications, and outreach have allowed HESI to build a multitude of new partnerships with high visibility, high impact organizations around the globe. Updates on future efforts are available via the HESI website or staff.

RECENT ACHIEVEMENTS:

- **Building Awareness & Community:** Inaugural Workshop and Partner Development. December 2012 Inaugural Workshop, *Towards New Science for Public Health, Arlington, VA*. Included ~50 global participants drawn from traditional HESI stakeholders (academe, industry, govt) as well as new partners (World Bank, Innovation and Entrepreneurship Experts, Biomedical and Nutrition Foundations, US Department of Commerce, and others).

- **Fostering Discussion:** CITE Seminar Series (March 2013, September 2014, March 2014). HESI-sponsored and CITE-themed seminars hosted at EuroTox and Society of Toxicology.

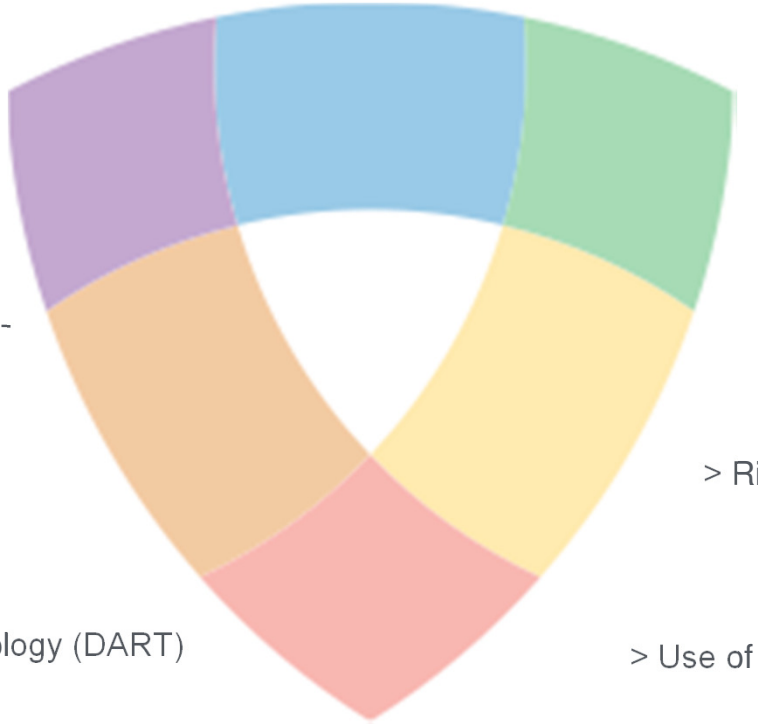
- **Calling for Change:** CITE-themed publication by SD Pettit, 'From silos to multi-lingual science' published in *Science Translational Medicine* (6:223, 2014).

- **Innovating Partnerships & Alliances:** HESI continues to build new partnerships across sectors to enhance the efficiency and uptake of impactful scientific research. This includes a focus on constructing effective teams, ensuring availability of relevant training and experience, and supporting skilled translation of research to application.

Just one example.... HESI is actively exploring opportunities to bridge space and life sciences via collaboration with NASA, the UK Space Agency, and other academic, industry, and global health foundation partners to enhance the heat-stability of critical medications.

HESI: 2014 Scientific Portfolio

TECHNICAL COMMITTEES



> Animal alternatives in environmental risk assessment

> Application of genomics to mechanism-based risk assessment

> Biomarkers of nephrotoxicity

> Cardiac safety

> Developmental and reproductive toxicology (DART)

> Genetic toxicology

> Immunotoxicology

> Protein allergenicity

> Risk assessment in the 21st century (RISK21)

> Sustainable chemical alternatives

> Use of imaging for translational safety assessment

> Development of methods for a tiered approach to assess bioaccumulation of chemicals

EMERGING ISSUES SUBCOMMITTEES

> Translational biomarkers of neurotoxicity

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ANTITRUST STATEMENT

The Branches and Institutes of ILSI, including their respective Boards of Trustees, Scientific Advisors, Scientific Directors, Members, Committees, Subcommittees, Task Forces, and Working Groups, meet to promote understanding and resolution of significant health, nutrition, and safety issues that confront the public, industry, and government. With this goal in mind, ILSI meetings should be occasions where members' representatives and other invited participants:

1. Discuss scientific solutions to problems affecting the health, nutrition, and safety of the public.

2. Develop means to contribute to proper analysis of public health, nutrition, and safety issues by regulatory bodies.

3. Review industrial activities and problems with implications for public health, nutrition, and safety, and review new scientific developments.

4. Support and promote research and educational programs to enhance public health, nutrition, and safety.

5. Develop objective and voluntary industry standards to promote health and safety and compliance with regulatory requirements.

ILSI meetings shall not be occasions where members' representatives and other invited participants:

1. Discuss prices or pricing policies, or any marketing policy with a direct or indirect effect on pricing or any other terms of sale.

2. Confer about division or allocation of sales territories or customers.

3. Establish blacklists or boycotts of suppliers, purchasers, or competitors.

4. Coerce members to implement particular programs or policies.

5. Resolve problems unique to a single member or a small, select group of members.

6. Exchange or disseminate information relating to costs of production, distribution, or marketing.

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CODE OF ETHICS & ORGANIZATIONAL STANDARDS OF CONDUCT

Statement of Purpose

The goal of the International Life Sciences Institute's (ILSI) Code of Ethics and Organizational Standards of Conduct is to assure that ILSI members, scientific advisors, consultants, other key stakeholders in ILSI scientific activities, and users of ILSI's scientific work products are aware of the ethical principles guiding the organization's structure and the tenets behind the organization's adherence to rigorous, peer-reviewed scientific investigation and scientifically balanced, evidence-based work products. All scientists who work with ILSI shall be provided with a copy of this document.

Introduction

The International Life Sciences Institute is an international organization that seeks to promote [the] public health through the advancement of peer-reviewed scientific investigation and application of evidence-based decision-making in the areas of nutrition, food safety, toxicology, risk assessment, and the environment. ILSI accomplishes its mission through support of scientific research, publications, and workshops and conferences and other scientific activities. The principles listed below provide a framework to guide ethical decision-making. (Note: Reference below to policies applicable to "ILSI" includes ILSI, ILSI branches, and the ILSI Research Foundation.)

Principle 1. Scientific Integrity

All ILSI projects must have a primary public purpose and benefit, and must address issues of broad public health interest.

The ILSI, ILSI branch and ILSI Research Foundation Boards of Trustees must be composed of at least 50 percent public sector members (primarily academic); the remaining trustees represent ILSI member companies. ILSI's trustees serve in a voluntary capacity; they are not paid for their time and are not personally eligible to receive grants from the ILSI entity on whose Board they sit.

ILSI shall only support animal and human subject research that has been approved by the appropriate bodies responsible for ensuring humane and ethical treatment of the animals or human subjects (e.g., Institutional Review Boards, Ethical Clearance Committees, Animal Care and Use Assurance Committee, etc.). All ILSI-supported research shall be conducted to meet the highest scientific standards as well as all applicable legal standards.

All ILSI sponsored research shall be conducted objectively and transparently so that the structure of the research is presented factually and without bias; be verifiable and reproducible.

ILSI encourages publication of all research results, regardless of outcome. ILSI entities shall not control the content of publications of research grantees or commissioned authors, but shall encourage academic freedom.

All ILSI research grantees must include language in their grant-related publications identifying the sponsor and providing appropriate sponsor contact information.

All ILSI committees and task forces must have scientific advisors from academia or government to ensure multi-sector input and balance, [and ILSI will only undertake activities for which there is broad interest and support.] All compensation (honoraria) provided to advisors must be disclosed by the advisors to the committee or task force overseeing the work.

Members of ILSI committees or task forces who are in attendance at meetings, symposia, or workshops must identify themselves on registration forms and materials by their primary affiliation (i.e., employer).

ILSI will be transparent in the disclosure of its funding sources.

Principle 2. Conflict/Declaration of Interest/Bias
ILSI believes that ensuring balance of perspectives is the most appropriate way to ensure that the impact of any potential conflict of interest or bias is minimized and does not exert an undue influence on the scientific process.

To this end, ILSI operates with transparency, conducts activities objectively, and is accountable to all stakeholders.

ILSI trustees must declare any potential bias or interest, including but not restricted to financial interests, and may be asked to recuse themselves from voting on issues that might be construed as conflicts of interest.

With respect to publications, grant reviews, and expert panels, ILSI expects the scientists with whom it works to [disclose] declare any potential [conflicts of] financial interest. ILSI may ask scientists to excuse themselves from an activity based on such a declaration.

Scientists who work with ILSI are expected to act in accordance with their own institution's conflict of interest policies and with applicable laws, as well as comply with the conflict of interest policies of any journal or organization with which they may work, including ILSI.

Principle 3. Advocacy
Advocacy of any kind is strictly limited to promotion of the use of evidence-based science as an aid in decision-making. ILSI does not conduct lobbying activities.

Principle 4. Transparency in Meetings and Publications
The purpose of and funding sources for all ILSI sponsored meetings, symposia, conferences, seminars and workshops will be fully disclosed in meeting materials.

All invited presenters will provide declarations of financial interest to be disclosed if relevant at the time of the meeting (orally or in the meeting materials).

All ILSI publications must reflect the high standards of the organization. ILSI-sponsored manuscripts must undergo stringent peer-review by qualified reviewers. Editors and reviewers will treat manuscripts under review as confidential. Scientists are expected to recuse themselves as editors or reviewers of manuscripts if past or present connections with the author(s) preclude an objective evaluation of the work.

Authors of ILSI-sponsored publications shall make full, signed disclosures of financial and/or other interests (e.g., industry relationships, advisory relationships, or other conflicts of interest) that would reasonably appear to affect the contents of the article.

All ILSI publications, including proceedings from workshops or symposia sponsored by ILSI branches, the Research Foundation or international committees will utilize appropriate attribution language to denote funding sources and sponsors, and ILSI entities shall provide contact information in all publications they produce for anyone interested in obtaining additional information about the organization or the specific sponsors of a particular project.