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HESI®

# Strength in Numbers

Highlights of HESI Activities

From June 2014 to June 2015

- **1,000** scientists actively involved in HESI projects
- **250** institutions contributing to HESI science
- **5** continents where HESI science was presented
- **14** new projects launched from within standing HESI Committees
- **3** new papers published per month, on average
- **>13,000** downloads of HESI peer-reviewed publications



For more information on the science and support behind the numbers, please contact HESI at [hesi@hesiglobal.org](mailto:hesi@hesiglobal.org).





**HESI**<sup>®</sup>

# Supporting Safe & Effective Medicines

HESI's novel experimental research, data sharing, and consensus-building programs provide essential information to benefit patients around the globe.

## Impact



### One Example

In the early 1990s, reports of unexpected and potentially lethal cardiac effects from over-the-counter medications gained international media attention. In response, HESI convened scientists from academe, industry, and regulatory agencies worldwide, to conduct novel collaborative research in this area. The HESI project team published their data and recommendations for improved testing strategies. These HESI data now underpin new global safety standards that have largely eliminated this problem worldwide.

### Many More...

Over its 25 year history, HESI's scientific contributions have enhanced the discovery, safety, and efficacy of medicines in many ways. HESI is a platform for collaborative effort to move research concepts into applications that benefit health.

## Research



### Developing Biomarkers

HESI projects span from the discovery and evaluation of predictive or toxicity markers in preclinical models, to the application of these markers for drug development decision-making, to their clinical use to protect the safety of patients.

### Characterizing Organ Toxicities

Global expert groups on cardiac, renal, neural, genetic, and immune systems are developing critical data on both adverse and adaptive responses in response to drugs.

### Translating Technology

HESI experts develop consensus on the application of new research tools and experimental models (e.g., genomic sequencing, imaging, in silico modeling, novel in vivo/in vitro systems, etc.) for drug safety.

Assessing Sensitivity. HESI's multi-partner research programs are optimal platforms for evaluating the sensitivity and reproducibility of scientific methods, markers, & technologies.

## Emerging Science



### Responsive Research

HESI's vibrant and nimble scientific research portfolio reflects changing and emerging human health challenges.

For example, HESI projects are exploring novel safety testing strategies and mechanistic studies in response to the most rapidly growing area of new drug development, immunotherapies. HESI's scientific portfolio also includes research in the rapidly evolving area of therapeutic & predictive use of stem cells.

### Open Call

HESI invites scientists, worldwide, with expertise and interest in drug safety and efficacy to join HESI's research programs and suggest new research priorities. For more information, contact [hesi@hesiglobal.org](mailto:hesi@hesiglobal.org)





# ILSI

## ANTITRUST STATEMENT

This policy has been adopted by the Board of Trustees of the International Life Sciences Institute. It applies to all staff, trustees, directors, members, advisers, task forces, committees, working groups, and members of the International Life Sciences Institute and its branches and affiliated entities (collectively ILSI).

ILSI is a scientific and charitable organization committed to scientific inquiry and education in the public interest. All activities and discussions connected with ILSI should be directed to promoting understanding and resolution of significant scientific challenges in human and environmental health, nutrition, and safety.

No activity or discussion at any meeting of ILSI or other function may be engaged in for the purpose of bringing about any understanding or agreement among members to (a) raise, lower, or stabilize prices; (b) regulate production; (c) allocate markets; (d) encourage boycotts; (e) foster unfair trade practices; (f) assist monopolization, or (g) in any way violate applicable antitrust, anti-monopoly, or competition laws.

ILSI meetings shall not be occasions where 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 or
7. Conduct or plan any lobbying activities.

Any questions regarding the meaning or applicability of this policy, as well as any concerns regarding activities or discussions at ILSI meetings, should be promptly brought to the attention of the Chair of the ILSI Board of Trustees or ILSI's legal counsel.

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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.