

ILSI North America is a public, nonprofit, scientific foundation with branches around the world that provides a forum to advance the understanding of scientific issues related to the nutritional quality and safety of the food supply. ILSI North America carries out its mission by sponsoring relevant research programs, professional education programs and workshops, seminars, and publications, as well as by providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. The programs of ILSI North America are supported primarily by the ILSI North America industry membership.

## **ILSI NORTH AMERICA POLICY ON CONFLICT OF INTEREST**

ILSI's Code of Ethics and Organizational Standards of Conduct assures 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. 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 and ILSI branch Boards of Trustees must be composed of at least 50% public sector members (primarily academic); the remaining trustees represent ILSI's member companies. ILSI's trustees serve in a voluntary capacity; they are not paid for their time.

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 animals or human subjects (e.g., Institutional Review Boards, Ethical Clearance Committees, Animal Care and Use Assurance Committees, etc.). All ILSI-supported research shall be conducted to meet the highest standards as well as all applicable legal standards.

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.

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 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.

With respect to publications, grant reviews, and expert panels, ILSI expects the scientists with whom it works to disclose any potential conflicts of interest. ILSI may ask scientists to excuse themselves from an activity.

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 to 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. Publications**

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 a manuscript if past or present connections with the author(s) preclude an objective evaluation of the work.

All ILSI publications, including proceedings from workshops or symposia sponsored by ILSI branches or entities 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.

## **Guiding Principles for ILSI NA- or Committee-Sponsored Activities with Respect to Conflicts of Interest**

The goal of ILSI NA's statement on conflicts of interest is to ensure that ILSI NA operates with transparency, conducts research activities objectively, and is accountable to all stakeholders.

### **A. Presentations at scientific or other meetings.**

1. If ILSI NA is a sponsor of a session, a statement about its purpose and funding will be made as well the ILSI NA committee involved and member companies sponsoring the committee.
2. In inviting presenters, a signed disclosure of their relevant interests (financial conflicts, relevant advisory, consulting or sponsorship arrangements of the speaker) shall be obtained and filed in ILSI NA offices (note: additional detailed guidance needs to be developed)
3. In the session, the relevant interests of the presenters shall be announced orally by the presenter or cited in the program
4. External funding of the presentation by ILSI NA and/or other sponsors shall be mentioned by name in programs or by other forms of disclosure, if applicable

### **B. Publications**

1. ILSI NA-sponsored and self-published books and monographs

Publications that are self-published by ILSI NA shall reflect the high standards of the organization. To that end -

- a. Authors should make a full signed disclosure of financial interests that would reasonably appear to affect the contents of the article or work's communication. This includes disclosure of industry relationships, advisory relationships, financial and other conflicts of interest. (note: additional detailed guidance needs to be developed)
- b. Relevant interests (financial and otherwise) and/or advisory relationships of the authors shall be cited in publications. It is recognized that guarding against conflicts of interest is important in all research, not simply industry-sponsored publications, but it is especially important in these.
- c. Authors shall adhere to accepted guidelines for authorship and publications (e.g. <http://www.jcmje.org/#author>).
- d. External funders of the research and/or other sponsors shall be mentioned (identified?) by name in publications and other forms of disclosure, if applicable.
- e. Ghost authorship and guest authorship are not appropriate in ILSI NA-sponsored studies or publications.
- f. Disclosure forms will be provided at or before the time the manuscript is received by ILSI NA.

2. ILSI NA–ILSI journals and books (Nutrition Reviews, Present Knowledge of Nutrition, etc.) The relevant editors and editorial boards will be contacted and urged to collaborate in the same spirit.
  - a - e above are recommended
3. Publication in other print media, such as articles and supplements in journals, chapters contributed to books, and monographs published by other parties, etc.
  - a - e above apply
4. Publication in other media such as internet websites, podcasts, etc.
  - a - e above apply if the content has a listed author

### **C. Research Grants and Projects sponsored by ILSI NA**

These principles apply to all parties participating in ILSI NA committee-sponsored research projects and grants to ensure the integrity of the work. ILSI NA representatives and researchers must:

1. Conduct the research objectively so that the structure of the research is presented factually and without bias and be such that it is verifiable and reproducible and is not geared solely toward producing the desired outcome for the sponsor.
  - a. The research will be designed so that it is a reasonably powerful and unbiased test of the hypothesis or question being evaluated. Investigators should maintain their intellectual honesty in proposing and performing all aspects of research so that it is uninfluenced by competing interests, including financial interests.
  - b. The research and its design will be formulated with significant input from the principal investigator.
  - c. Remuneration for work and other tokens of appreciation will never depend on the outcome or interpretation of the research. It does not preclude stopping studies using pre-specified adaptive designs to permit a change in course when the original purpose of the study appears to be futile or dangerous. It also does not prejudge deciding which, if any, new work is to be undertaken on the basis of results of a prior study. The research should be based on observable phenomena.
  - d. At present, ILSI NA is not involved as a sponsor of phase 3 clinical trials. However, if in the future ILSI NA does become involved in sponsoring such clinical trials, investigators are strongly encouraged to register the trial at [clinicaltrials.gov](http://clinicaltrials.gov) and to establish a data safety and monitoring board as well as meeting all other requirements of the relevant Human Investigations Review Committee. All adverse events must be reported immediately to the appropriate body, usually the Food and Drug Administration.

2. Operate with transparency to advance the research and promote trust of both colleagues and the public by being open and willing to accept scrutiny. This involves:
  - a. Full and regular internal reporting and external disclosure of financial interests that would reasonably appear to affect the welfare of subjects or the conduct or communication of research.
  - b. Disclosure of industry relationships, financial and other conflicts of interest when communicating to the public, other investigators, their institutions, and journals. Relevant interests and/or advisory relationships of the researchers shall be cited in publications and other forms of disclosure. It is recognized that guarding against conflicts of interest is important in all research, not simply industry-sponsored research.
  - c. The principal investigator is free to publish the results of the study. Publication of the results of the scientific research is encouraged irrespective of whether the results are favorable to the sponsor or not. This should be specified in the written contract and protocol. The scientist shall always be free to publish the findings of the research within a period of time specified in advance in the written contract or protocol. The researcher shall adhere to accepted guidelines for authorship and publication (e.g. <http://www.jcmje.org/#author>). If the principal investigator has not pursued publication in accordance with the contract, ILSI NA or the sponsoring committee may seek another author or coauthor to produce and publish the work.
  - d. The method of publication shall be stipulated in the contract. ILSI NA and the principal investigator shall consult about publication in a scientific journal, but the principal investigator will have the final say on the contents, the authors, the form of publication and where the research will be published.
  - e. External funders of the research and/or other sponsors shall be mentioned by name in publications and other forms of disclosure.
  - f. Ghost authorship and guest authorship are not appropriate in ILSI NA-sponsored studies.
  
3. Be accountable to all stakeholders
  - a. Investigators are personally accountable for complying with the requirements of the funding agreements with ILSI NA and their institution's policies, and for ensuring the care and safety of human subjects.
  - b. Investigators have the right and obligation to publish.

### **Board and Committee Service**

- A. ILSI NA does not pay its trustees for their service on the Board of Trustees or on committees or as advisors to ILSI NA committees. However, it may reimburse their expenses. No trustee may be paid for time spent as an ILSI NA trustee by anyone other than his or her regular employer.

- B. Board members who serve as advisors must recuse themselves from votes on issues that might be construed as conflict of interest including evaluation of grants to their institutions. A trustee and his or her immediate family members may not be the recipient of an ILSI NA grant. An organization or individual (other than an immediate family member) with which a trustee is associated is not thereby precluded from receiving an ILSI NA grant. Where a trustee has an affiliation with a grant applicant or other interest that may lead to or suggest influence in ILSI NA's decision relating to a grant, the trustee must disclose to the affiliation or interest to the Board Chair and must recuse himself or herself from all Board decisions relating to the grant.
- C. Board members must disclose all conflicts of interest.

### **Advisors**

- A. Advisors and committee members must disclose all conflicts of interest.
- B. Committee advisors are offered a modest honorarium plus expenses for attending related meetings and committee business. The financial arrangements are negotiated in a contract signed by the ILSI NA advisor yearly. All such arrangements will be disclosed at committee meetings.

### **Expectations for ILSI NA's Guiding Principles for Collaborations**

The same transparency and disclosures for funding are expected from potential collaborators, as demonstrated by written guidelines that are shared by ILSI NA staff.

### **Enforcement**

It is the responsibility of the members of the ILSI NA Board of Trustees, committees, and staff to adhere to these guidelines, and for staff to audit adherence to principles and reporting of compliance.

*Approved 31 July 2008 by the ILSI North America Board of Trustees.*

## **ILSI North America Conflict of Interest Guiding Principles**

The guiding principles were proposed in a recent article **“Funding food science and nutrition research: financial conflicts and scientific integrity.”** This paper was peer reviewed by a broad-based group of nearly 40 scientists from health-related fields, as well as by the editors and reviewers of these six scientific journals – *Nutrition Reviews (NR)*, *American Journal of Clinical Nutrition (AJCN)*, *Journal of the American Dietetic Association (JADA)*, *Journal of Food Science*, *Nutrition Today*, and the *Journal of Nutrition*. The journals all published the paper, in full or in part, in April, May, and June, 2009.

The principles proposed in the paper provide guidance to researchers receiving funding from industry to help minimize the potential for bias due to funding source. The paper also was published to stimulate ongoing discussion of the conflict-of-interest issue because of the common desire of food and nutrition scientists and practitioners, journal editors, academics, government representatives and members of the relevant industries to protect the integrity of the scientific

food and nutrition literature. A pdf of the full article in *Nutrition Reviews* is available on the ILSI NA website at <http://www.ilsina.org/>. Your comments and opinions are welcomed.

In the conduct of public/private research relationships, all relevant parties shall:

1. conduct or sponsor research that is factual, transparent, and designed objectively; according to accepted principles of scientific inquiry, the research design will generate an appropriately phrased hypothesis and the research will answer the appropriate questions, rather than favor a particular outcome;
2. require control of both study design and research itself to remain with scientific investigators;
3. not offer or accept remuneration geared to the outcome of a research project;
4. prior to the commencement of studies, ensure that there is a written agreement that the investigative team has the freedom and obligation to attempt to publish the findings within some specified time-frame;
5. require, in publications and conference presentations, full signed disclosure of all financial interests;
6. not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations;
7. guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers; and
8. require that academic researchers, when they work in contract research organizations (CRO) or act as contract researchers, make clear statements of their affiliation; require that such researchers publish only under the auspices of the CRO.