

## SCIENTIFIC INTEGRITY IN ILSI ENTITY ACTIVITIES

**1. ILSI's Mission.** ILSI is a nonprofit, worldwide network whose mission is to provide science that improves human health and well-being and safeguards the environment.

**2. ILSI's Fundamental Values.** The global ILSI network is organized and operated as a nonprofit, charitable and scientific organization. As such, ILSI entities must always act in the service of the public good rather than in the service of corporate or other private interests. ILSI's activities include the participation of and contributions from scientists working in industry, academia, government, civil society, and other sectors. Many entities in the ILSI network receive substantial funding from industry collaborators, and many ILSI entities also receive critically important financial support from international organizations, government agencies, and private foundations, as well. Several ILSI entities work with volunteering scientists, who receive only token or no compensation for their in-kind support of our activities. The contributions of time, money, and expertise that ILSI entities receive from multiple sources are provided upon the shared understanding that ILSI's work is scientifically rigorous, scrupulously neutral, and free from improper influence by the sources of its funding. For all these reasons, each ILSI entity must first and foremost conduct itself and its activities in a transparent manner, with a view to serving the public interest.

**3. ILSI's Commitment to Scientific Integrity.** All ILSI entities must strive to achieve and maintain the highest standards of scientific integrity in all their activities. For this purpose, "scientific integrity" means "the condition that occurs when persons adhere to accepted standards, professional values, and practices of the relevant scientific community. Adherence to these standards ensures objectivity, clarity, and reproducibility, and utility of scientific and scholarly activities and assessments and helps prevent bias, fabrication, falsification, plagiarism, outside interference, censorship and inadequate procedural and information security."<sup>\*</sup>

### **4. Selection, Development, and Conduct of ILSI Entity Activities.**

- (a) All significant scientific and programmatic activities of the entity—including but not limited to committee activities, research projects, meetings, and official ILSI programs and presentations at meetings of other entities—shall be selected in accordance with a process approved by the entity's board.
- (b) In deciding whether to undertake any activity, and in executing such activities after such a decision has been taken, the entity shall ensure that the activities:
  - (i) fit with the broad mission of ILSI and the specific objectives of the ILSI entity;
  - (ii) are carried out in a scientifically legitimate and accurate manner and free from

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<sup>\*</sup> See Scientific Integrity Principles and Best Practices: Recommendations from a Scientific Integrity Consortium (2018) (submitted for publication in *Science & Engineering Ethics* and currently in peer review). This manuscript is a work of the international Scientific Integrity Consortium convened by ILSI North America and the National Academies of Sciences, Engineering, and Medicine's Government-University-Industry Research Roundtable. The manuscript's definition of scientific integrity is drawn from U.S. government agencies' policies that were reviewed and deemed accurate and appropriate by the Scientific Integrity Consortium.

- bias;
  - (iii) include the substantial participation of public sector scientists;
  - (iv) conform to ILSI's policies and specifically are not for the primary purpose of advancing the interest of any private sector entity(ies) that provide funding for the activities;
  - (v) produce outcomes that are not determined by the source of funding for the activities;
  - (vi) do not involve the endorsement or advertising of any particular brand or company product, or display of sponsor or other company logos;
  - (vii) include disclosure of relevant facts and important information where their omission would present an unbalanced view of an issue in which a financial contributor to the entity has an interest.
- (c) Except in special circumstances described herein, an entity shall not undertake any scientific or programmatic activity that is funded solely by industry financial supporters unless it has at least three financially distinct funding providers. The purpose of this rule is to avoid undue domination of the activity by a company, and to ensure that the activity is directed to issues of broad, public interest, rather than commercial interests. An exception to this rule exists for non-research awards (such as scholarships and grants that facilitate recipients' participation in university or government-sponsored training programs) when ALL of the following circumstances are present:
- (i) The activity has been approved pursuant to a transparent process carried out by a committee of board members or an external scientific advisory group whose members are independent of the sponsor(s).
  - (ii) The performance of the activity will be overseen by a body of scientific advisors who are independent of the sponsor(s).
  - (iii) The funding agreement with the sponsor(s) clearly establish that the sponsor(s) have no authority to alter or predetermine the outcome of any scientific activity, and that the entity and its collaborators are required to exercise their independent judgment regarding the conduct of the activities and the outcomes of those activities.
- (d) ILSI entities will be transparent in the disclosure of their funding sources. The purpose of and funding sources for all ILSI entity-sponsored meetings, symposia, conferences, seminars and workshops will be fully disclosed in meeting materials.
- (e) All ILSI entity committees and task forces must have scientific advisors from academia or government to ensure multi-sector input and balance.
- (f) Members of ILSI committees or task forces who attend meetings, symposia, or workshops must identify themselves on registration forms and materials by their primary affiliation (i.e., employer).
- (g) With respect to, ILSI entities will require all authors of entity-supported publications and all participants in grant reviews, and expert panels to declare any potential conflicts of financial interests. The ILSI entity may ask scientists to excuse themselves from an activity based on such a declaration.

- (h) Scientists who work with ILSI entities must comply with their own institutions' conflict of interest policies and with applicable laws, as well as ILSI's policies and the conflict of interest policies of any journal or organization with which they may work.

#### **5. Conduct of ILSI Entity-Hosted Meetings.**

- (a) The purpose of and funding sources for all ILSI entity meetings, symposia, conferences, seminars and workshops will be fully disclosed to meeting attendees in meeting materials.
- (b) All invited presenters at meetings of ILSI entities will provide declarations of financial interest to be disclosed to meeting attendees at the time of the meeting (orally or in the meeting materials).

#### **6. Research Projects, Commissioned Research, and Research Grants Awarded by an ILSI Entity.**

When an ILSI entity undertakes a research project, commissions scientists to conduct research, or awards a research grant to a third party such as a university or research institute, the ILSI entity shall ensure that the following principles<sup>†</sup> are respected:

- (a) **The research must be factual, transparent, and designed objectively, and, 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.**
- (b) **Both the study design and the research itself must at all times be under the control of the scientific investigators.** *Once a design, protocol, or implementation plan has been established for a project, investigators shall not be required to accept suggestions or changes to the design, protocol, or implementation, or to resulting manuscripts, which are proposed by the ILSI entity or by other entities involved in funding the work in question. This principle 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 not of significant importance from the standpoint of concern for health or the environment. It also does not preclude deciding which, if any, new work is to be undertaken on the basis of results of a prior study.*
- (c) **The scientific investigators must not be offered or accept remuneration geared to the outcome of the research project.**
- (d) **The ILSI entity must ensure, before the commencement of studies, 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.**
- (e) **The ILSI entity must require, in publications and conference presentations, full signed disclosure of all financial interests of the scientific investigators.**
- (f) **The ILSI entity must not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations.**

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<sup>†</sup> The bold text in this paragraph 6 is taken from the eight guiding principles on the conduct of public/private research relationships published in S. Rowe, et al., Funding food science and nutrition research: financial conflicts and scientific integrity, *Nutrition Reviews*, Volume 67, Issue 5, 1 May 2009, Pages 264–272. Additional clarification, based upon existing ILSI practices, is provided in the italicized text.

- (g) **The ILSI entity must guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers.**<sup>‡</sup> *Such accessibility may be ensured by requiring the scientific investigators to deposit project data and code in publicly-available “open data” repositories.*
- (h) **The ILSI entity must require academic researchers, when they work in contract research organizations (CRO) or act as contract researchers, to make clear statements of their affiliation; and require that such researchers publish only under the auspices of the CRO.**

The ILSI entity shall provide a copy of these principles regarding commissioned research and research grants to all investigators engaged in such research.

**7. Publications.** Publications of ILSI entities (whether self-published or items published in third-party peer-reviewed journals or other media) shall reflect the high standards of the organization. To that end:

- (a) ILSI entity-sponsored manuscripts must undergo stringent peer-review overseen by the respective journal. If ILSI arranges the peer review, 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.
- (b) Authors of publications sponsored by ILSI entities are required to fully disclose their employment affiliations and all 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.
- (c) Relevant interests (financial or otherwise) and/or advisory relationships of the authors shall be cited in publications in accordance with the journal’s disclosure policies. 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.
- (d) Authors shall adhere to accepted guidelines for authorship and publications.
- (e) External funders of the research, sponsors, and any other entities that have provided funds to the ILSI entity to facilitate or enable any part of the research activity shall be identified by name in publications and other forms of disclosure.
- (f) 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.
- (g) Ghost authorship (when an individual makes a substantial contribution to the research or the writing of the manuscript but is not listed as an author) is not allowed in ILSI entity-sponsored studies or publications.

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<sup>‡</sup> In rare cases, despite an ILSI entity’s best efforts, some or all data or materials cannot be shared for personal privacy, intellectual property, legal or ethical reasons. See OECD (2015), "Promoting data-driven scientific research", in *Data-Driven Innovation: Big Data for Growth and Well-Being*, OECD Publishing, Paris, <https://doi.org/10.1787/9789264229358-11-en>. In such cases, the ILSI entity- funded researcher/s will make a publicly available statement of this omission at the time of submission.