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## **MANDATORY POLICIES OF THE INTERNATIONAL LIFE SCIENCES INSTITUTE**

**1. Binding Effect of these Policies.** The Board of Trustees of the International Life Sciences Institute (“ILSI”) has adopted these policies (including their Appendices) as *mandatory* for all ILSI entities throughout the world.<sup>1</sup> Because the ILSI entities have agreed in their charter agreements to adhere to policies established by the ILSI Board of Trustees as a condition of their membership in the ILSI Federation, those entities are contractually obligated to adhere to these policies.

**2. The Policies.** Each ILSI entity (and, as applicable, its Board of Trustees, staff, and representatives) shall comply with the policies that are contained in exhibits listed below.

**Appendix A.** Scientific Integrity in ILSI Entity Activities.

**Appendix B.** Board Governance of the ILSI Entity.

**Appendix C.** Management and Operation of the ILSI Entities.

**Appendix D.** Commentary on Legislative and Regulatory Matters.

**Appendix E.** Rules for ILSI Attendance at and/or Representation before Authoritative Bodies, Assemblies, or Officials.

**Appendix F.** Anti-Corruption Policy.

**Appendix G.** Antitrust Statement.

**Appendix H.** Diversity Policy.

**Appendix I.** Statement on Tobacco Products and the Companies that Produce and Sell Them.

**3. Implementation.** These policies are effective for all ILSI entities as of the date of their adoption by the ILSI board. Accordingly, within 60 days following the adoption of these policies, each ILSI entity shall:

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<sup>1</sup> As used herein, the word “entity” includes the International Life Sciences Institute (“ILSI”), any ILSI branch, association, foundation, focal point, and all other legal entities that purport to act in the name of ILSI by virtue of a charter agreement with ILSI.

- a) Bring its governance, operations, and activities into compliance with these policies; and
- b) Communicate these policies to each member of its board, each of its employees, and each of its volunteers and collaborators, and shall ensure that these policies are at all times readily accessible to such persons.

**4. Compliance Monitoring.** Because the failure of one ILSI entity to adhere to these policies could detrimentally affect some or all other members of the ILSI Federation, ILSI shall take measures to ensure that all ILSI entities implement and comply with these policies, and to correct violations of these policies. All ILSI entities shall fully cooperate with ILSI, and supply all information requested by ILSI, in ILSI's efforts to verify and enforce compliance with these policies.

**5. Enforcement.** ILSI's legal counsel shall have primary responsibility and authority to monitor, investigate, and verify compliance by ILSI entities with these policies, and may work with ILSI entities on plans to aid them in bringing their activities into compliance. ILSI's legal counsel shall report to the ILSI board of trustees on a regular basis regarding ILSI entity compliance with these policies. The ILSI board shall evaluate each ILSI entity's compliance. Where the ILSI board or its executive committee determines that an ILSI entity has materially violated these policies, in its sole discretion the ILSI board or the executive committee may direct the entity to take corrective action and/or impose sanctions, up to and including suspension or termination of the entity's charter agreement and its association with ILSI.

**6. Review and Revision of Policies.** ILSI shall review and revise these policies on a periodic basis. In doing so, ILSI shall take into account, among other things, relevant scientific best practices, legal developments, and the advice of the ILSI entities.

These policies were revised by the ILSI Board of Trustees in its regularly scheduled meeting on November 20, 2023.

## APPENDIX A – SCIENTIFIC INTEGRITY IN ILSI ENTITY ACTIVITIES

**1. ILSI’s Mission.** ILSI is a nonprofit, worldwide federation (the “ILSI Federation”) whose mission is to provide science that improves human health and well-being and safeguards the environment.

**2. ILSI’s Fundamental Values.** The ILSI Federation is organized and operated as a global network of nonprofit, charitable and scientific organizations. 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 Federation 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>2</sup>

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

(a) All significant scientific and programmatic activities of the entity—in-

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<sup>2</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.

cluding 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 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 the commercial display of sponsor or other company logos<sup>3</sup>;
  - (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

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<sup>3</sup> This provision does not prohibit the display of sponsor or other company products or logos in connection with ILSI entity meetings or presentations, so long as the meeting or presentation contains objective scientific and educational merit, and the display of the products or logos does not consist primarily of advertising or the promotion of the presenter’s goods or services. These Mandatory Policies also do not prohibit the display at an ILSI entity event or presentation of the logos of companies or organizations that have provided financial or other significant contributions in support of the event or presentation. ILSI entities that wish to display other parties’ logos must first obtain the permission of the owner of the logo.

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) 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>4</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.**
- (g) **The ILSI entity must guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers.**<sup>5</sup> *Such accessibility may be ensured by requiring the scientific investigators to deposit project data and code in publicly-available "open*

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<sup>4</sup> The bold text in this paragraph 5 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.

<sup>5</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.

*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.

## APPENDIX B – BOARD GOVERNANCE OF ILSI ENTITIES

- 1. Role of Entity Boards.** Each ILSI entity shall be governed by a board of trustees, which is responsible for ensuring that:
  - A.** The entity is created, composed, and operated in a manner consistent with the applicable laws, rules, and regulations of the country(ies) where it is incorporated.
  - B.** The entity acts in accordance with the ethical and organizational standards set forth in the organization’s charter agreement with ILSI, its governing instruments, and these policies.
  - C.** The board exercises effective oversight over the management and finances of the entity and provides strategic direction to entity management. Such oversight requires board approval of budgets and supervision of programs, committees, and activities to ensure their sustainability, scientific merit, and adherence to these policies.
- 2. Tripartite Participation on ILSI Boards.** At least half of the trustees of an ILSI entity board must be considered “public sector” trustees as defined in these policies. To be considered a public sector trustee, the individual must be able to demonstrate that he or she is substantially and actively engaged in teaching, research, and/or administrative programs of a public institution (university, nonprofit research institute, foundation, or a governmental, intergovernmental or quasi-government body). To the extent permitted by local laws, regulations, and public policies, and when it is feasible to do so, each ILSI entity should strive to include on its board individuals employed by government entities.
- 3. Equality of All Trustees.** All trustees of an ILSI entity shall have the equal right, authority, opportunity, and obligation to participate in the governance of the ILSI entity, without regard to whether they are considered public sector trustees or industry trustees.
  - A. Duty of Loyalty to the Entity.** Each ILSI entity shall communicate to all of its trustees that, whether they are employed in the public or private sector, each of them serves in an individual capacity, and not as agents of their employers. All actions taken in one’s capacity as a trustee of an ILSI entity must be in the best interest of that ILSI entity, which must not be subordinated to the interest of the trustee’s employer.
  - B. No Compensation for Board Service.** Trustees shall not be compensated



by an ILSI entity for serving on the board or any committee. However, to the extent permitted by applicable law, the entity may reimburse the reasonable and necessary costs of attending official functions of the entity. An ILSI entity shall not make loans of its funds to trustees.

**C. Internal Controls and Financial Records and Policies.** Each ILSI entity board must ensure that the entity has in place effective internal controls, systems of checks and balances, and formalized record keeping, which are consistent with the aims of safeguarding the assets of the entity; assuring compliance by the entity with applicable laws, rules, regulations, and these policies; and adhering to the public interest mission of ILSI. At a minimum, such internal controls shall include the following:

- i. keeping detailed books, records, and accounts which accurately and fairly reflect the transactions and dispositions of assets;
- ii. regular financial reporting to the board by the entity's management;
- iii. a system of internal controls which provides reasonable assurances that grants, transactions and other expenditures are properly authorized and appropriately recorded;
- iv. policies for incurring and reimbursement of reasonable travel and other expenses;
- v. educating staff regarding who can authorize particular transactions;
- vi. ensuring that multiple staff members and/or trustees in the organization understand the flow of monies through the entity; and
- vii. providing sufficient information to the board to give assurance that the entity's investment portfolio is being responsibly managed, consistent with applicable investment guidelines.

**4. Governance Records and Policies.** Each ILSI entity board must ensure that the entity maintains the following written records and policies:

- A.** copies of current organizational documents such as articles of incorporation (or articles of association) and bylaws;
- B.** official minutes of meetings and actions of the entity's board of trustees, recorded reasonably promptly after the meeting or action in question;

- C.** a policy requiring trustees to declare conflicts of interests no less frequently than annually;
- D.** a whistleblower policy that protects employees and other entity personnel against retaliation for reporting suspected financial irregularities; and
- E.** a document retention policy that provides for the safekeeping of key entity documents and the prevention of their destruction upon receiving notice of a legal inquiry into the entity's operations.

## **APPENDIX C – MANAGEMENT AND OPERATION OF THE ILSI ENTITIES**

- 1. Executive Director Position.** The day-to-day operations of each ILSI entity shall be managed and directed by an Executive Director who shall be responsible to the entity board. The entity shall establish a clear job description or terms of reference for the Executive Director position, which will be periodically reviewed by the board. The Executive Director shall not be a voting member of the entity board.
- 2. Executive Director Evaluation and Compensation** - The board of each ILSI entity shall evaluate the Executive Director's performance no less than annually. Compensation of the Executive Director shall be established in accordance with a process approved by the board, and the full board shall have access to information about the Executive Director's compensation. Compensation levels shall be fair, reasonable, and not excessive, and should take into account the nature and amount of work required by the Executive Director, as well as benchmarks from comparable institutions when such information is available.
- 3. No Credit or Loans of Entity Funds to Staff.** An ILSI entity shall not extend credit, including personal loans, to its Executive Director or other staff member, or any family member of any such persons.
- 4. Communications Management.** In its external communications, each ILSI entity must strive to ensure that it exemplifies ILSI's values of scientific excellence, rigor, and integrity; financial and legal probity; and paramount dedication to the public interest. Each entity shall avoid making public statements that are inconsistent with these policies, such as statements that amount to lobbying, advocacy of policy positions to be taken by public authorities, or advancement of commercial interests. Entities should be aware that any public statement made by that entity can reflect on the entire organization. ILSI entities shall consult with ILSI prior to making public statements on issues that could impact negatively on other member entities of the ILSI Federation.
- 5. Use of the ILSI Name and Logo.** In its relations with corporate organizations, each ILSI entity must avoid any conflict of interest and act at all times in only in a manner that will enhance the credibility and professional recognition of the entity and of the global ILSI Federation. An ILSI entity shall not authorize any use of the ILSI name and logo: (a) in connection with activities in which the entity has no substantive involvement; or (b) in any manner that could impact negatively upon ILSI's or the entity's credibility or repu-

tation, such as by allowing corporate donors or member companies to display the ILSI name or logo in connection with their products, advertisements, or promotional literature. If an ILSI entity places its name or the ILSI logo on any publication, statement, or communication, the entity must ensure that the contents of that publication, statement, or communication conform to the standards set forth in these policies.

**6. Adherence to Applicable Law.** All ILSI entities shall comply with all applicable laws, regulations, court orders, and other binding rules established by public authorities. To the extent that the requirements imposed by such laws, rules, court orders, and other binding rules differ from the requirements established in ILSI's Mandatory Policies in terms of their permissiveness, an ILSI entity shall comply with the more stringent of the two standards.

## **APPENDIX D – ADVOCACY AND PROVISION OF INFORMATION TO REGULATORS**

- 1. Prohibition on Advocacy Activities.** ILSI entities shall not engage in advocacy of any kind. They may provide evidence-based scientific information to decision-makers to enable them to make fair and fully informed decisions.
- 2. No Commentary on Public Policy Matters.** ILSI entities shall not comment upon or propose public policy solutions in relation to proposed, pending, or existing legislation (i.e., statutory law established by a parliament or other legislative arm of government). This prohibition applies whether or not a communication or statement refers to a specific bill, law, or other legislative measure.
- 3. Provision of Scientific Information Relevant to Regulation.** With regard to proposed, pending, or existing regulations (i.e., rules established by administrative bodies to implement legislation), ILSI entities may provide regulators information relating to factual matters within ILSI's scientific expertise, but they may not directly or indirectly propose public policy solutions or advocate the commercial interests of their member companies or other parties. All commentary on regulatory matters by any ILSI entity in any part of the world must be reviewed and approved by ILSI's legal counsel in advance of its submission to any public authority.

## **APPENDIX E – ATTENDANCE AT AND/OR REPRESENTATION BEFORE AUTHORITATIVE BODIES, ASSEMBLIES, OR OFFICIALS**

ILSI is often invited to attend meetings of authoritative bodies such as the Codex Alimentarius. When it does attend such meetings, ILSI participates as an **observer** rather than as a decision maker. In such circumstances, ILSI may send a delegation to the meeting. All such delegations must be assembled and conducted in accordance with the procedures set out in this memorandum.

As a U.S. tax-exempt charitable organization that has adopted globally applicable policies and standards of conduct, ILSI is committed to ensure that its activities always strictly adhere to certain general principles. One of these is that no ILSI entity may engage in any activity that can be characterized as being designed to specifically influence a given course of legislation or advocacy to advance a specific interest. Another is that all ILSI activities must serve a paramount "public interest" and not be performed for the benefit of ILSI member companies. Moreover, under no circumstances may ILSI entities advocate the commercial interests of member companies or other parties.

ILSI has also adopted the following specific rules governing the participation of ILSI-led delegations to meetings of Codex and other intergovernmental organizations and bodies:

### **COMPOSITION OF DELEGATION**

- All ILSI delegations must be headed by an ILSI entity staff member. They cannot be headed by a representative of a member company or any other invitee.
- If delegates from multiple ILSI entities attend the same meeting, they are to assemble as a single delegation that will be headed by the ILSI entity staff member who first requested registration to the meeting.

### **PROVISION OF COMMENTARY AT THE MEETING**

- If the ILSI delegation is going to make a presentation or address the body in any way, the presentation or statement must be made by an ILSI entity staff member.
- Each ILSI entity that invites someone to be a delegate must ensure that the delegate understands and agrees to these principles.
- ILSI may provide written or oral comments to the international body. Any comments must comply with the following requirements:
  - o All comments must be reviewed in advance by ILSI's Global Executive Director and legal counsel. To allow sufficient time for review, comments should

be submitted to the Global Executive Director no later than 30 days prior to the meeting.

- The comments must consist of scientific information relevant to activities ILSI has undertaken that relate to the issues under discussion. They may call attention to relevant peer-reviewed publications and publications by authoritative bodies.
- ILSI may not advocate a position on a regulatory or legal text or policy that the body is considering. Specifically, there shall be no attempt to persuade a decision maker towards a particular outcome.
- The comments must be balanced and objective. They must not state or imply that there is a consensus if there is a significant lack of scientific agreement. On the other hand, if there is no significant disagreement, the comments should not imply that there is.

## **POST-MEETING REPORT**

- The delegation must prepare a written report of the meeting that they attend and deliver it to ILSI's Global Executive Director and legal counsel within 30 days following the meeting. Reports should clearly describe what transpired at the meeting, the scientific issues raised, and next steps determined. If an ILSI delegate spoke to the meeting, the exact nature of the discussion (topic under discussion, specifics of the ILSI delegate's remarks, and questions addressed to the delegate, with answers provided) must be detailed in the report. The report should be balanced and objective.

At such meetings, it may be perceived that the comments of ILSI attendees reflect an official ILSI position even when they engage in informal discussions, such as during breaks, receptions, or before/after the meeting. Accordingly, even in such informal discussions, ILSI delegates should refrain from all advocacy and comply with the rules stated above. In addition, ILSI delegates must bear in mind that when attending such meetings, they represent ILSI, not their employer. They are not permitted to set aside their capacity as an ILSI representative in order to advocate their employers' position.

## APPENDIX F – ANTI-CORRUPTION POLICY

***Maintaining a Corruption-Free Culture.*** The ILSI Federation is committed to sustaining a culture free from corruption in transactions between government officials and employees and other representatives of ILSI. Bribes, loans, and other illicit compensation offered or paid to government officials can subject the individuals and organizations who provide them to very serious civil and criminal penalties, including fines, debarment from government contracting, court supervision, and—for individuals—imprisonment. Moreover, engaging in corrupt practices could severely damage the public trust that organizations such as ILSI seek to cultivate through their work in support of global public health.

### ***Statement of ILSI Policy.***

1. It is the policy of ILSI that each of our trustees, employees, staff, agents, representatives, and other third parties that interact with government officials on behalf of ILSI shall comply with the anti-bribery laws of the countries where ILSI engages in activities.
2. Bribery of any kind, in any country, regardless of local custom or practice, is strictly prohibited.
3. No ILSI trustee, employee, staff, agent, representative, vendor or any other third party with which ILSI works shall make any payment or provide anything of value, directly or indirectly, to any official or employee of any government, state-owned enterprise, or international organization (an “Official”), in order to induce such Official to do or omit to do any act in violation of the lawful duty of such official; or to influence that Official to secure any improper advantage for ILSI or for ILSI’s member companies. This policy includes, but is not limited to, a prohibition on obtaining or retaining business, or directing business to any person or entity.
4. No ILSI funds shall be used to make contributions to political parties or candidates for elected office in any country.
5. It is also the policy of ILSI that each of its employees, staff, agents, representatives, vendors and all third parties that work with ILSI make and keep books, records, and accounts, which, in reasonable detail, accurately reflect any transactions and dispositions of ILSI.
6. To the extent permitted by applicable national and local law, ILSI may reimburse travel expenses and provide meals and entertainment to Officials as part of a legitimate ILSI business activity, so long as the benefit to the Official remains reasonable. In all such cases, the benefit should be merely incidental to the business purpose and should not be intended or likely to be perceived as an attempt improperly to influence the Official’s decision in any matter.



**Scope of Policy.** As used in this policy, “ILSI” means the International Life Sciences Institute and all ILSI Federation member entities throughout the world. Representatives of ILSI who are covered by this policy include employees, officers, and agents of companies that are members of ILSI when those persons are acting for ILSI in a representative capacity. In addition to the civil and criminal fines and penalties imposed by applicable anti-corruption laws, violators of this ILSI policy may be subject to disciplinary measures imposed by ILSI. Penalties for violations will vary with the circumstances, but may include termination of the offender’s relationship with ILSI.

**Compliance.** ILSI shall develop training and other educational materials for the individuals covered by this policy to ensure that the policy is fully understood and implemented. ILSI’s staff in its Washington, DC headquarters shall serve as a clearinghouse for requests for information and clarification by such individuals.

## **APPENDIX G – ANTITRUST STATEMENT**

This policy applies to all staff, trustees, directors, members, advisers, task forces, committees, working groups and other bodies of the International Life Sciences Institute and member entities of the ILSI Federation (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.

## **APPENDIX H – DIVERSITY POLICY**

The ILSI Federation is committed to promoting access, equity, and inclusiveness; and to discouraging discrimination based on race, color, disability, national origin, religion, ethnicity, gender, age, socio-economic status, and other forms of discrimination that deny the essential humanity of all people. Accordingly, in both the hiring of staff and the appointment of members of their Boards of Trustees, ILSI Federation member entities will refrain from all forms of discrimination that are prohibited by applicable law and will work to establish a genuinely diverse workplace and governing body.

## APPENDIX I – ILSI STATEMENT ON TOBACCO PRODUCTS AND COMPANIES THAT PRODUCE AND SELL THEM

**Health Risks of Tobacco Products.** Scientific evidence overwhelmingly supports the consensus that there is no safe level at which tobacco products may be smoked.<sup>6</sup> Smokers as well as infants, children, and adults exposed to secondhand tobacco smoke face elevated risks of death and other serious health conditions, which can include (among others) cancer; heart, liver and lung disease; stroke; frequent and severe asthma attacks; respiratory infections; ear infections; sudden infant death syndrome (SIDS); and pregnancy complications.<sup>7</sup> Likewise, the consumption of smokeless tobacco products can lead to nicotine addiction and has been strongly linked to cancer of the mouth, esophagus, and pancreas.<sup>8</sup> The U.S. Centers for Disease Control and Prevention (CDC) state that electronic cigarettes— variously known as “e-cigs,” “e-hookahs,” “mods,” “vape pens,” “vapes,” “tank systems,” and “electronic nicotine delivery systems”— “have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products.”<sup>9</sup> However, the CDC further states that, e-cigarette use is “not safe for youth, young adults, pregnant women, or adults who do not currently use tobacco products.”<sup>10</sup>

**ILSI Support of Tobacco Control Policies and Measures.** The International Life Sciences Institute (ILSI) does not ordinarily take positions on questions of public policy. However, for the reasons described above, the consumption of tobacco products constitutes a unique threat to the health of the public, with no compensating benefits to society. Accordingly, ILSI supports aggressive efforts to cease or reduce all tobacco use, including smoked tobacco products; smokeless tobacco products; and electronic cigarettes and their associated liquids containing nicotine and other harmful agents. ILSI also supports the objectives, guiding principles, and general obligations of the World Health

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<sup>6</sup> National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta (GA): Centers for Disease Control and Prevention (US); 2014. 2, Fifty Years of Change 1964–2014. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK294310/>; JAMA Internal Medicine (12/05/16) Inoue-Cho, Maki; Liao, Linda M.; Reyes-Guzman, Carolyn; et al.

<sup>7</sup> CDC Fact Sheet - Health Effects of Secondhand Smoke, [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/secondhand\\_smoke/health\\_effects/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/health_effects/index.htm) (accessed November 22, 2018).

<sup>8</sup> CDC Fact Sheet – Smokeless Tobacco: Health Effects, [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/smokeless/health\\_effects/index.html](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/smokeless/health_effects/index.html) (accessed November 22, 2018).

<sup>9</sup> CDC - About Electronic Cigarettes (E-Cigarettes), [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/about-e-cigarettes.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html) (accessed November 22, 2018).

<sup>10</sup> *Ibid.*

Organization Framework Convention on Tobacco Control,<sup>11</sup> and endorses the measures described in the Framework Convention.

**Prohibition on ILSI Entity Relationships with Tobacco Companies.** The ILSI entities have never granted membership to organizations directly involved in the production, marketing, or sales of tobacco products. In 2001, ILSI adopted a rule specifically prohibiting such memberships, prohibiting ILSI entities to work on tobacco-related research, and providing that no ILSI entity may accept financial or other contributions—restricted or unrestricted—from any tobacco company. For a time, ILSI admitted as member companies a small number of food business subsidiaries and divisions of conglomerates that also, in separate lines of business, were involved in production and sales of tobacco products. In January 2015, ILSI forbade ILSI entities to accept as members companies whose affiliated entities—including parent, subsidiary, or sibling corporations or co-divisions—engage in the manufacture, production, marketing, sale, or distribution of tobacco products.

In light of the rules and developments described above, ILSI entities are prohibited from engaging in the following activities and practices:

- Accepting as members, companies that, either directly or through an affiliate, engages in the Manufacture, production, marketing, sale, or distribution of tobacco products (Tobacco Companies);
- Accepting funds from Tobacco Companies for any purpose;
- Engaging in or sponsoring research relating to tobacco products;
- Permitting employees, agents, or representatives of Tobacco Companies to participate in ILSI entity governance or activities; and
- Inviting employees, agents, or representatives of Tobacco Companies to attend ILSI entity activities.

Any violation by an ILSI entity of these prohibitions will be treated as a serious breach of the ILSI Mandatory Policies, for which an ILSI entity may be sanctioned, including by expulsion from the ILSI network. Reports by ILSI staff, trustees, and other collaborators of alleged violations are subject to the protections of ILSI's whistleblower policies. Members of the public who have evidence of alleged violations of these prohibitions are encouraged to provide such evidence to ILSI's ILSI Global Executive Director and General Counsel.

*First adopted by the ILSI Board of Trustees on 8 January 2019.*

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<sup>11</sup> WHO Framework Convention on Tobacco Control, <http://www.who.int/fctc/en/> (accessed November 22, 2018).