

MANDATORY POLICIES OF THE INTERNATIONAL LIFE SCIENCES INSTITUTE

1 Introduction and Scope

1.1 Binding Effect of these Policies. The Board of Trustees of the International Life Sciences Institute (“ILSI”) has adopted these policies as *mandatory* for all ILSI entities throughout the world.* Pursuant to the entities’ charter agreements with ILSI, the entities are contractually obligated to adhere to these policies.

1.2 Nature of ILSI. ILSI is organized and operated as a nonprofit, charitable and scientific organization. It is required by law always to 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. The contributions of time, money, and expertise that ILSI receives 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 of these reasons, each ILSI entity must first and foremost conduct itself and its activities with a view to serving the public interest.

2 Board Governance of the ILSI Entity

2.1 Role of Entity Boards. Each ILSI entity shall be governed by a board, 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.

2.2 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

* 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.

(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.

2.2 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.

2.3 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.

2.4 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.

2.5 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:[†]

- (a) keeping detailed books, records, and accounts which accurately and fairly reflect the transactions and dispositions of assets;
- (b) regular financial reporting to the board by the entity's management *January 2016*
- (c) a system of internal controls which provides reasonable assurances that grants, transactions and other expenditures are properly authorized and appropriately recorded;
- (d) policies for incurring and reimbursement of reasonable travel and other expenses;
- (e) educating staff regarding who can authorize particular transactions;
- (f) ensuring that multiple staff members and/or trustees in the organization understand the flow of monies through the entity; and
- (g) providing sufficient information to the board to give assurance that the entity's investment portfolio is being responsibly managed, consistent with applicable investment guidelines.

[†] ILSI's legal counsel and chief financial officer are available to assist ILSI entities in complying with these requirements.

2.6 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.

3 Management and Operation of the ILSI Entity

3.1 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.

3.2 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.

3.3 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.

3.4 Communications Management. In its external communications, each branch 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

[‡] ILSI's legal counsel is available to assist ILSI entities in complying with these requirements.

reflect on the entire organization. ILSI entities shall consult with ILSI prior to making public statements on issues that could impact negatively on other members of the ILSI network.

3.5 Funding of ILSI Activities.

(a) All significant scientific and programmatic activities of the entity, including but not limited to committee activities, shall be adopted 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;
- (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) do not involve the endorsement or advertising of any particular brand or company product, or display of sponsor or other company logos;
- (vi) 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 sponsors unless it has at least three financially distinct funding sponsors. The purpose of this rule is to avoid undue domination of the activity by the sponsoring company(ies), and to ensure that the activity is directed to issues of broad, public interest, rather than merely the commercial interests of the sponsor(s). 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.

3.6 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 network. 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 reputation, 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.

3.7 Commissioned Research and Research Grants Awarded by an ILSI Entity. When an ILSI entity commissions one or more scientists to conduct research, and when an ILSI entity awards a research grant to a third party, the ILSI entity shall ensure that the following principles are respected:

- (a) The research shall be conducted in an objective manner so that its results are presented factually and without bias or predetermined outcomes and be such that it is verifiable and repeatable.
- (b) The research shall be designed so that it is an adequate and unbiased test of the hypothesis or question being evaluated. Investigators must maintain their intellectual honesty in proposing and performing all aspects of research so that it is uninfluenced by competing interests, including financial interests.
- (c) The scientific independence, autonomy, and integrity of the investigators involved must be respected. Without limitation, this means that 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, by corporate sponsors, or by other entities involved in funding the work in question.
- (d) Remuneration for work and tokens of appreciation for investigators shall not depend on the outcome or interpretation of the research. 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.
- (e) The ILSI entity shall provide a copy of these principles regarding commissioned research and research grants to all investigators engaged in such research.

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

- (a) Authors are required to make a full 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.
- (b) Relevant interests (financial or 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.
- (d) 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.
- (e) 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.

4 Representation of ILSI Entities in Meetings of Government Agencies, International Organizations, and Other Authoritative Bodies.

4.1 Commentary on Legislative and Regulatory 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. 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.

4.2 Official ILSI Participation in Meetings of Public Bodies. When an ILSI entity participates in a meeting of a public body (e.g., Codex Alimentarius, OECD, FAO, WHO, etc.), only staff members of the entity are authorized to speak as representatives of the entity in such meetings.

5 Additional Policies

5.1 Anti-Corruption Policy. ILSI entities are bound by the [ILSI Anti-Corruption Policy](#), which shall be distributed to trustees and staff of the ILSI entity as well as any person, company, or organization that acts or purports to act on behalf of the ILSI entity.

5.2 Antitrust Policy. ILSI entities are bound by the [ILSI Antitrust Statement](#), which shall be distributed to participants in meetings of the ILSI entity.

5.3 Code of Ethics and Standards of Conduct. Each ILSI entity—together with its employees, trustees, agents, and other representatives—is bound by the [ILSI Code of Ethics and Standards of Conduct](#).

5.4 Diversity Policy. ILSI entities are bound by the [ILSI Diversity Policy](#), which shall be distributed to trustees and **staff of the ILSI entity**.

5.5 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 these policies in terms of their permissiveness, an ILSI entity shall comply with the more stringent of the two standards.

6 Implementation, Compliance Monitoring, and Enforcement

6.1 Implementation. These policies are effective for all ILSI entities as of the date of their adoption by the ILSI board. Accordingly, within 270 days following the adoption of these policies, each ILSI entity shall:

- (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.

6.2 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 network, 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.

6.3 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 an annual basis regarding ILSI entity compliance with these policies. The ILSI board shall evaluate each ILSI entity's compliance. Where the ILSI board determines that an ILSI entity has materially violated these policies, in its sole discretion the ILSI board 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.

6.4 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 adopted by the ILSI Board of Trustees in its regularly scheduled meeting on January 23, 2016.